

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* 1st as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Arizona Administrative Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 2. ADMINISTRATION

CHAPTER 5. DEPARTMENT OF ADMINISTRATION PERSONNEL ADMINISTRATION

PREAMBLE

1. **Sections Affected:** R2-5-303. **Rulemaking Action:** Amend
2. **The specific authority for rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
Authorizing statutes: A.R.S. § 41-763
Implementing statutes: A.R.S. § 42-763(6)
3. **The effective date of the rules:**
August 5, 1997
4. **A list of all previous notices appearing in the Register addressing the final rule:**
Notice of Rulemaking Docket Opening: 3 A.A.R. 1150, April 25, 1997
Notice of Proposed Rulemaking: 3 A.A.R. 1168, May 2, 1997
5. **The name and address of agency personnel with whom persons may communicate regarding the rule:**
Name: Gordon Carrigan, Human Resources Generalist
Address: Department of Administration
1831 West Jefferson, Room 107
Phoenix, Arizona 85007
Telephone: (602) 542-4784
Fax number: (602) 542-2796
6. **An explanation of the rule, including the agency's reasons for initiating the rule:**
The adopted rulemaking articulates the authority of the Director to establish salaries for employees whose position classifications and/or salaries are affected by a Classification Maintenance Review (CMR) or Special Market Adjustment (SMA). The rule is needed to allow for adjustments of more than 2.5% for salaries that are significantly below the market rate that is established by the CMR or SMA, because the current rule can be interpreted as having a cap of 2.5% for all adjustments. The amendment will provide clarification.
7. **A showing of good cause why the rule is necessary to promote statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**
Not applicable.
8. **The summary of the economic, small business and consumer impact:**
The adopted rule will not affect small businesses and consumers. The impact is upon employees whose salaries are substantially below the market as determined by a CMR or SMA study. The funds are provided by the Legislature and are not charged against an agency's budget. The cost is substantial for SMA's and CMR's as evidenced by \$974,500 being expended during Fiscal Year 1997 (1/97) and \$2,467,400 being provided for Fiscal Year 1998.
9. **A description of the changes between the proposed rules, including supplemental notices, and final rules:**
No changes were made.
10. **A summary of the principle comments and the agency response to them:**
The Department did not receive any public comments.

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11. Any other matters prescribed by statute that are applicable to the specific agency or to or to any specific rule or class of rules:
Not applicable.
12. Incorporations by reference and their locations in the rules:
None.
13. Was this rule previously adopted as an emergency rule?
No.
14. The full text of the rules follows:

TITLE 2. ADMINISTRATION

CHAPTER 5. DEPARTMENT OF ADMINISTRATION
PERSONNEL ADMINISTRATION

ARTICLE 3. CLASSIFICATION AND COMPENSATION

affected by a Classification Maintenance Review or a
Special Market Adjustment.

Section
R2-5-303. Salary Administration

- C. No change.
- D. No change.
- E. No change.
- F. No change.
- G. No change.
- H. No change.
- I. No change.
- J. No change.
- K. No change.
- L. No change.
- M. No change.
- N. No change.
- O. No change.

ARTICLE 3. CLASSIFICATION AND COMPENSATION

R2-5-303. Salary Administration

- A. No change
- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. The Director shall establish guidelines that shall super-
sede the provisions of subsections (B)(1), (2), and (3)
when setting the salary of an employee in a classification

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TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected:
R4-23-110
R4-23-410
- Rulemaking Action:
Amend
New Section
2. The specific authority for rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):
Authorizing statutes: A.R.S. § 32-1904(A)(1)
Implementing statutes: A.R.S. §§ 32-1901(7) and (59) and 32-1904(B)(5)
3. The effective date of the rules:
August 5, 1997
4. A list of all previous notices appearing in the Register addressing the final rule:
Notice of Rulemaking Docket Opening: 1 A.A.R. 229, March 24, 1995
2 A.A.R. 3596, August 16, 1996
Notice of Proposed Rulemaking: 3 A.A.R. 1126, April 25, 1997
5. The name and address of agency personnel with whom persons may communicate regarding the rule:
Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
5060 North 19th Avenue
Phoenix, Arizona 85015
Telephone: (602) 255-5125, ext. 131

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Fax Number: (602) 255-5740

6. An explanation of the rule, including the agency's reasons for initiating the rule:

This rule was initiated at the request of the Arizona Pharmacy Association. The Arizona Pharmacy Association represents pharmacies and pharmacists in the state of Arizona. In the fall of 1994, a committee consisting of members from the Arizona Pharmacy Association worked together to draft a proposed compounding statute. The proposal was presented at the July 17-18, 1996, Board meeting. The Board determined that a statutory change was not necessary. The Board directed the Board staff to work with the Arizona Pharmacy Association committee in converting the proposed statute into a proposed rule. This rule is the culmination of that joint effort.

The rule amends R4-23-110 by adding a definition for "current good compounding practices" and amending the definitions of "component" and "lot number" or "control number". The rule adds a new Section, R4-23-410 (Current Good Compounding Practices). The rule establishes the minimum current good compounding practices for the preparation of drugs by a pharmacist licensed by the Board, in a pharmacy permitted by the Board, and according to applicable state law governing the practice of pharmacy. The rule establishes standards for all aspects of compounding practice include:

- a. Receipt, storage, or use of drug substances;
- b. Limiting quantity and advertising;
- c. Organization, training, and personnel;
- d. Security, safety, and quality;
- e. Compounding facilities, equipment, and utensils;
- f. Control procedures for components and drug product container and closures;
- g. Drug compounding controls; and
- h. Labeling and recordkeeping.

The Board believes that adoption of these rules will benefit the public health and safety by establishing clear standards governing pharmacy compounding practice. These standards will ensure compounded drug product safety identity, strength, quality, and purity. The Board further believes that specific regulation and enforcement are necessary to regulate and control the rapidly evolving role of pharmacists in a dynamic health care system.

7. A showing of good cause why the rule is necessary to promote statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

8. The summary of the economic, small business and consumer impact:

In today's average pharmacy, the art of compounding is almost a lost art. Drug companies manufacture the vast majority of the drugs dispensed in today's pharmacies. Although drug companies manufacture most drugs, there still exists the need for a dosage form or strength of drug that is not available commercially. For example, a drug may only come in tablet form but a particular patient may require a liquid or suppository. Many physicians use a compounding pharmacist or pharmacy to provide individualized doses or dosage forms. These compounded drugs can literally mean life or death or, at least, reduced pain and suffering for a physician's patient. The rule benefits the Board, pharmacies, pharmacists, physicians, 3rd-party payers, and patients by providing standards to ensure drug product safety, identity, strength, quality, and purity and further benefits the Board by promoting consistent compliance. Pharmacies and pharmacists may benefit from reduced liability by following standards established in the rule. Pharmacies and pharmacists will benefit because the rule is concise and compliance standards are clear. Third-party payers and patients benefit from lower cost therapy by using the proper drug, in the lowest therapeutically effective dose, with fewer side effects, in a dosage form that provides optimal patient compliance, resulting in a positive therapeutic outcome. The benefits for Arizona citizens provided by compounding pharmacists and pharmacies, although non quantifiable, far outweigh the additional costs the proposed rule may impose on compounding pharmacists and pharmacies.

9. A description of the changes between the proposed rules, including supplemental notices, and final rules:

There were no changes in the text of the proposed rule as published by the Secretary of State and the text of the rule as finally adopted. However, after review of the adopted final rule by GRRC staff and upon their recommendation, the following changes occurred. To increase the clarity, conciseness, and understandability of R4-23-410, nonsubstantive, grammar, punctuation, and format changes occurred at subsections:

1. (B)(1) - the word "or" is deleted;
2. (B)(3) - in line 2 the word "provide" is changed to "provides" and a new subsection (B)(4) is created out of the last sentence of the subsection;
3. (C)(1)(a) - the comma is deleted and the word "and" is inserted between the words "containers" and "closures";
4. (D)(1) - the comma is deleted and the word "and" is inserted between the words "containers" and "closures" and the word "labeling" is inserted after the word "materials";
5. (E)(3) - a hyphen is inserted between the words "temperature" and "controlled", a comma is inserted after the word "compounding", and the word "comply" is changed to "complies";
6. (G) - the word "preparing" is changed to "compounding"; and
7. (J)(1)(d) - the 1st "e" in judgement is deleted.

The GRRC staff also identified the need to amend the definition of "lot number" or "control number" because it is used in the rule and the existing definition only relates to manufacturing. The definition is amended to include compounding.

After consultation with GRRC staff, the Board decided to change the wording of the new subsection (B)(4) created in #2 above. The change puts a period after the word "services" and deletes the language from the word "but" to the end of the sentence. This part of the sentence prohibited advertising of a specific drug product. After reviewing the GRRC staff's investigation of the public comment regarding the possible violation of 1st amendment rights concerning this subsection's language, the Board believes that the particular language would violate the 1st amendment. Since the removal of this language in effect removes a burden, the change is nonsubstantive and provides a clear, understandable, and constitutional rule.

10. A summary of the principle comments and the agency response to them:

One written comment was received. The comment was not against the rule itself but rather voiced opposition to the use of the words "manufacturing" and "manufacture" in the definitions with the word "compounding". The comment resulted from a misunderstanding of the use of the definitions Section of the rules. Verbal and written dialogue with the individual resulted in understanding and agreement with the rule package. A public hearing on the proposed rulemaking was held on May 27, 1997. Four individuals attended the hearing and each individual signed in as being for the proposed rulemaking. Three individuals made verbal comments. One individual did express some concern about the language in the last sentence of R4-23-410(B)(3). The sentence deals with soliciting business by advertising or otherwise promoting the compounding of a specific drug product. There was considerable debate about this particular subject by the Arizona Pharmacy Association committee that proposed these rules to the Board. This same subject was debated nationally by the National Association of Boards of Pharmacy and the United States Pharmacopeia Convention while drafting their respective model rules and guidelines. Each of these groups decided to leave the language as written in this rule. The Board agrees with the above-named groups and will leave the advertising prohibition in the rule. There were no opposing comments received by the Board.

11. Any other matters prescribed by statute that are applicable to the specific agency or to or to any specific rule or class of rules:

Not applicable.

12. Incorporations by reference and their locations in the rules:

None.

13. Was this rule previously adopted as an emergency rule?

No.

14. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section

R4-23-110. Definitions

ARTICLE 4. PROFESSIONAL PRACTICES

Section

R4-23-410. Current Good Compounding Practices

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to the definitions set forth in A.R.S. § 32-1901, the following definitions apply to this Chapter.

"Active ingredient" means any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of man or other animals. The term shall include those components which may undergo chemical change in the manufacture of the drug and be present in the finished drug products in a modified form intended to furnish the specified activity or effect.

"AZPLEX" means Arizona pharmacy law examination.

"Batch" means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"Beyond-use date" means a date determined by a pharmacist and placed on a prescription label at the time of dispensing intended to indicate a time beyond which the contents of the prescription are not recommended to be used.

"Biological safety cabinet" means a containment unit suitable for the preparation of low- to moderate-risk agents where there is a need for protection of the product, personnel, and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, Revised June 1987 edition, incorporated by reference and on file with the Office of the Secretary of State.

"Class 100 environment" means an atmospheric environment in compliance with the Federal Standard 209 Clean Room and Work Station Requirements: Controlled Environment, publication FED-STD-209D, June 15, 1988, edition which included January 28, 1991, changes, incorporated by reference and on file with the Office of the Secretary of State.

"Community pharmacy" means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.

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"Component" means any ingredient intended for use in ~~compounding or manufacturing the manufacture of~~ drugs in dosage form, including ~~an ingredient~~ those that may not appear in the finished product.

"Correctional facility" has the same meaning as set forth in A.R.S. §§ 13-2501 and 31-341.

"Current good compounding practices" means the minimum standards for methods used in, and facilities or controls use for, compounding a drug to ensure that the drug has the identity and strength and meets the quality and purity characteristics it purports or is represented to possess.

"Cytotoxic" means a pharmaceutical that has the capability of killing living cells.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster, or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"First-aid stations" means units within a business or industrial organization which are limited to, as the name implies, first-aid treatment of injuries incurred in association with the business function.

"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

"Industrial medical stations" means units where drugs are stored, established within businesses and industrial organizations.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, is located in a correctional facility, and engages in the compounding, production, dispensing, and distribution of drugs.

"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and dispenses a majority of its prescription medications or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.

"Limited-service pharmacy permittee" means a person who has applied for and obtained a limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Lot" means a batch or any portion of a batch of a drug or in the case of a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures its uniformity, and in either case which is identified by a distinctive lot number and has uniform character and quality with specified limits.

"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the ~~compounding or manufacturing manufacture~~, control, packaging, and distribution of a batch or lot of a drug can be determined.

"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

"Mediated instruction" means learning transmitted via intermediate mechanisms such as audio and/or visual tape telephonic transmission, etc.

"NABPLEX" means National Association of Boards of Pharmacy Licensure Examination.

"Occupational Medicine" or "Industrial Medicine" means the field of medicine dealing with the medical problems associated with persons employed in any occupation.

"Outpatient" or "Outpatient setting" means a person that receives medical treatment as a result of not being a residential patient in a health care institution, or a location where medical treatment is provided to patients not required to be overnight residents of the facility.

"Patient profile" means a readily retrievable, centrally located information record which contains, but is not limited to: patient demographics, allergies, and medication profile.

"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules or regulations, offered by an Approved Provider.

"Prepackaged drug" means a drug which is packaged, ordinarily in frequently prescribed quantities, labeled, in compliance with A.R.S. §§ 32-1967 and 32-1968, for storage and subsequent dispensing by a pharmacist, or pharmacy intern under the supervision of a pharmacist, who at that time verifies that it is properly labeled for the patient.

"Provider pharmacist" means the pharmacist who supplies medication to a long-term care facility and maintains medication profiles.

"Remodel" means to structurally alter the pharmacy area or location.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

"Resident" means a person admitted to and residing in a long-term care facility.

"Sterile pharmaceutical product" means a dosage form free from living microorganisms.

"Strength" means:

The concentration of the drug substance (for example, w/w, w/v, or unit dose/volume basis); and/or

The potency, that is, the therapeutic activity of the drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Supervision" means the pharmacist shall be present, assume legal responsibility, and have personal oversight of activities relating to the acquisition, preparation, distri-

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bution, and sale of prescription medications by pharmacy interns or supportive personnel.

"Supplying" is the issuing of 1 or more doses of a proprietary drug in the original container of a manufacturer for subsequent use by the patient.

"Supportive Personnel" means an individual trained to perform activities related to the preparation and distribution of prescription medications, under the supervision of a pharmacist and consistent with policy and procedures as required in R4-23-403.

"Wholesale distribution" means distribution of drugs to persons other than a consumer or patient but does not include:

The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this Section, "emergency medical reasons" includes transfer of prescription drugs by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage;

The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

The sale, purchase, or trade of blood and blood components intended for transfusion.

"Wholesale distributor" means anyone engaged in wholesale distribution of drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least 5% of gross sales.

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-410. Current Good Compounding Practices

A. This rule establishes the current good compounding practices to be used by a pharmacist licensed by the Board, in a pharmacy permitted by the Board, and in compliance with applicable federal and state law governing the practice of pharmacy.

B. A pharmacy permittee shall ensure compliance with the provisions in this subsection.

1. All drug substances for compounding that are received, sorted, or used by the pharmacy permittee:
 - a. Meet official compendium requirements;
 - b. Are of high quality, such as Chemically Pure (CP), Analytical Reagent (AR), certified American Chemical Society (ACS), or Food Chemical Codex (FCC) grade; or
 - c. Are obtained from a source that, in the professional judgment of the pharmacist, is acceptable and reliable.
2. A pharmacist employed by the pharmacy permittee, compounds a drug in limited quantity in anticipation of receiving valid prescriptions for the drug, only after establishing a history of compounding valid prescriptions for the drug.
3. Neither the pharmacy permittee nor a pharmacist employed by the pharmacy permittee provides a compounded drug to a pharmacy, medical practitioner, or

other person for dispensing or distributing except that a compounded drug may be provided to a medical practitioner to administer to a patient of the medical practitioner.

4. A pharmacy or pharmacist may advertise or otherwise promote the fact that the pharmacy or pharmacist provides prescription compounding services.

C. A pharmacy permittee shall ensure compliance with the organization, training, and personnel issues in this subsection.

1. Before dispensing a compounded drug, a pharmacist:
 - a. Inspects and approves or rejects, or assumes responsibility for inspecting and approving or rejecting, components, drug product containers and closures, in-process materials, and labeling;
 - b. Prepares or assumes responsibility for preparing all compounding records;
 - c. Reviews all compounding records to ensure that no errors occur in the compounding process; and
 - d. Ensures the proper use, cleanliness, and maintenance of all compounding equipment.
2. A pharmacist engaged in compounding:
 - a. Complies with the current good compounding practices and applicable state pharmacy laws;
 - b. Maintains compounding proficiency through current awareness, training, and continuing education; and
 - c. Ensures that personnel engaged in compounding wear:
 - i. Clean clothing appropriate to the work performed; and
 - ii. Protective apparel, such as coats, aprons, gowns, gloves, or masks to protect the personnel from chemical exposure and prevent drug product contamination.

D. A pharmacy permittee shall ensure the security, safety, and quality of a compounded drug by conforming with the following standards:

1. Implement procedures to exclude from direct contact with components, drug product containers and closures, in-process materials, labeling, and drug products, any person with an apparent illness or open lesion that may adversely affect the safety or quality of a compounded drug, until the illness or lesion, as determined by competent medical personnel, does not jeopardize the safety or quality of a compounded drug; and
2. Require all personnel to inform a pharmacist of any health condition that may adversely affect a compounded drug.

E. A pharmacy permittee shall provide compounding facilities that conform with the standards in this subsection.

1. In addition to the minimum area requirements of R4-23-609, R4-23-655, or R4-23-673, the compounding area:
 - a. Complies with the requirements in R4-23-604(C)(1) and R4-23-611; and
 - b. Has sufficient space to permit efficient pharmacy practice, free movement of personnel, and visual surveillance by a pharmacist.
2. If sterile pharmaceutical or radiopharmaceutical compounding is performed, provide a separate compounding area that complies with the rules governing sterile pharmaceuticals and radiopharmaceuticals.
3. A clean, dry, and temperature-controlled area and, if required, a refrigerated area, in which to store properly labeled containers of bulk drugs, chemicals, and materials used in compounding, that complies with state statutes and rules.

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- E.** To protect drug product safety, identity, strength, quality, and purity, a pharmacy permittee shall ensure that equipment and utensils used in drug compounding conform with the standards in this subsection:
1. Are of appropriate design, adequate size, and suitably located for proper operation, cleaning, and maintenance;
 2. Are made of material that is not reactive, additive, or absorptive when exposed to components, in-process materials, or drug products;
 3. Are cleaned and sanitized before use;
 4. If previously cleaned:
 - a. Are protected from contamination before use; and
 - b. Are inspected and determined suitable for use, by a pharmacist, immediately before initiation of compounding operations;
 5. Are routinely inspected, calibrated, or checked to make proper performance certain.
- G.** A pharmacy permittee shall ensure that the pharmacist-in-charge establishes and implements procedures to prevent cross-contamination when drug products that require special precautions to prevent cross-contamination, such as penicillin, are used in a compounding procedure. The procedures shall include either the dedication of equipment or the meticulous cleaning of contaminated equipment before its use in compounding other drugs.
- H.** A pharmacy permittee shall ensure that the pharmacist-in-charge establishes and implements control procedures for components and drug product containers and closures, either written or electronically stored with printable documentation, that conform with the standards in this subsection.
1. Components and drug product containers and closures are:
 - a. Stored off the floor,
 - b. Handled and stored to prevent contamination, and
 - c. Rotated so the oldest approved stock is used 1st.
 2. Container closure systems comply with official compendium standards.
 3. Drug product containers and closures are clean and made of material that is not reactive, additive, or absorptive.
 4. Drug product containers and closures used for compounded sterile pharmaceuticals and radiopharmaceuticals are handled, sterilized, and stored in compliance with R4-23-670, R4-23-681, and R4-23-682.
- I.** A pharmacy permittee shall ensure that the pharmacist-in-charge establishes and implements drug compounding controls that conform with the standards in this subsection.
1. Drug compounding procedures are available in either written form or electronically stored with printable documentation:
 - a. To ensure that a finished drug product has the identity, strength, quality, and purity it is purported or represented to possess, the procedures include, for each drug compounded, a description of:
 - i. The components, their amounts, the order of component addition, and the compounding process;
 - ii. The required equipment and utensils; and
 - iii. The drug product container and closure system proper for the sterility and stability of the drug as it is intended to be used.
 - b. To test the product being compounded, the procedures monitor the output and validate the performance of compounding processes that may cause variability in the final drug product, including assessing:
 - i. Dosage form weight variation;
 - ii. Adequacy of mixing to ensure uniformity and homogeneity; and
 - iii. Clarity, completeness, or pH of solutions.
 2. Components for drug compounding are accurately weighed, measured, or subdivided. To ensure that each weight, measure, or subdivision is correct as stated in the compounding procedures, a pharmacist checks and rechecks, or assumes responsibility for checking and rechecking, the operations at each stage of the compounding process.
 3. When a component is removed from its original container and transferred to another container, the new container label contains, in full text or an abbreviated code system, the following:
 - a. The component name,
 - b. The lot or control number,
 - c. The weight or measure,
 - d. The beyond-use date, and
 - e. The transfer date.
- J.** A pharmacy permittee shall ensure that the pharmacist-in-charge stores any quantity of compounded drug produced in excess of the quantity dispensed in accordance with subsection (B).
1. In an appropriate container with a label that contains:
 - a. A complete list of components or the drug product name;
 - b. The preparation date;
 - c. The assigned lot or control number; and
 - d. A beyond-use date based upon the pharmacist's professional judgment, but not more than the maximum guidelines recommended in the Pharmacy Compounding Practices chapter of the official compendium unless there are published data based on testing that show a longer period is appropriate; and
 2. Under conditions, dictated by the drug's composition and stability characteristics, that ensure its strength, quality, and purity.
- K.** A pharmacy permittee shall ensure that the pharmacist-in-charge establishes and implements recordkeeping procedures that comply with this subsection:
1. Drug compounding procedures and other records required by this Section are retained in the pharmacy for not less than 3 years; and
 2. Drug compounding procedures and other records required by this Section are readily available for inspection by the Board or its designee.

NOTICE OF FINAL RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 8. DEPARTMENT OF ENVIRONMENTAL QUALITY
WASTE MANAGEMENT

PREAMBLE

1. **Sections Affected:**

| | |
|-----------|-------|
| R18-8-260 | Amend |
| R18-8-261 | Amend |
| R18-8-262 | Amend |
| R18-8-263 | Amend |
| R18-8-264 | Amend |
| R18-8-265 | Amend |
| R18-8-266 | Amend |
| R18-8-268 | Amend |
| R18-8-270 | Amend |
| R18-8-271 | Amend |
| R18-8-273 | Amend |
2. **The specific authority for the rule making, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

General authorizing & implementing statute: A.R.S. § 49-922
3. **The effective date of the rules:**

August 8, 1997
4. **A list of all previous notices appearing in the Register addressing the final rule:**

| | |
|--------------------------------------|--------------------------------|
| Notice of Rulemaking Docket Opening: | 2 A.A.R. 4191, October 4, 1996 |
| Notice of Proposed Rulemaking: | 2 A.A.R. 1301, May 16, 1997 |
5. **The name and address of agency personnel with whom persons may communicate regarding the rule:**

| | |
|-------------|---|
| Name: | Lynn A. Keeling, Rules Specialist |
| Address: | Arizona Department of Environmental Quality 3033 North Central, Room 844A Phoenix, Arizona 85012-2809 |
| Telephone: | (602) 207-2223 or 800-234-5677 ext. 2223 (Arizona only) |
| Fax Number: | (602) 207-2251 |
| | or |
| Name: | Martha Seaman, Manager of Rule Development |
| Address: | Arizona Department of Environmental Quality 3033 North Central, Room 831 Phoenix, Arizona 85012-2809 |
| Telephone: | (602) 207-2222 or 800-234-5677 ext. 2222 (Arizona only) |
| Fax Number: | (602) 207-2251 |
6. **An explanation of the rule, including the agency's reasons for initiating the rule:**

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 - B. Descriptions of the revisions incorporated by reference.
 - C. Summary of state-specific changes.

THE EXPLANATION OF THE RULE

- A. General Information about the Incorporations by Reference as of July 1, 1996.

Every year the Arizona Department of Environmental Quality (ADEQ) amends the state's hazardous waste rules. The state's hazardous waste rules are generally comprised of the federal regulations, authorized by Subtitle C of the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), which are incorporated by reference. The hazardous waste rules are well established and have been effective since 1984. This year's

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amendments cover changes in the federal regulations promulgated between July 2, 1995, and July 1, 1996. In addition, 4 Federal Registers that were published after July 1, 1996, are incorporated by reference to include technical amendments, typographical errors, and change the effective dates of certain Federal Registers.

For Arizona to be authorized to manage the federal hazardous waste program, ADEQ must either incorporate by reference the federal regulations or write state rules that are equivalent to and consistent with federal regulations. Incorporating the federal regulations will keep Arizona's hazardous waste management program funded by the United States Environmental Protection Agency (EPA) and in compliance with A.R.S. § 49-922. The EPA requires that Arizona be re-authorized to maintain the authority to manage the federal hazardous waste program in lieu of the EPA administering the program in Arizona. ADEQ received final RCRA authorization in 1985 and continues to apply for re-authorization to keep current with changes to federal regulations. Adoption of federal regulations also promotes compliance uniformity among states. Most of the federal regulations incorporated by reference in this rulemaking are required for re-authorization.

The following changes are state-initiated and not required for re-authorization. However, the changes are reviewed by the EPA.

1. Acceptance of EPA-issued variances pursuant to 40 CFR 260.30 - 260.33.
2. The addition of clarification language to R18-8-260 to expressly state how generator status is determined for registration fee purposes required by ARS § 49-929.
3. Time-frames for submission of exception reports.
4. Amendment of 40 CFR 273 to include mercury-containing waste lamps as universal waste.

To identify the changes made to the incorporations by reference in the rules, the date has been changed from July 1, 1995, to July 1, 1996, in subsection (A) of most sections. Subsection (A) of Sections R18-8-260 through R18-8-266, R18-8-268, R18-8-270, R18-8-271, and R18-8-273 incorporates by reference the federal regulations published in 40 CFR 260 through 266, 268, 270, 273, and 124 as of July 1, 1996, with certain exceptions. Sections R18-8-269 and R18-8-280 are state rules that do not incorporate federal regulations.

The purpose of this rulemaking is primarily to incorporate the text of federal regulations for re-authorization by the EPA. Modifications to the text incorporated by reference are intended to make the language consistent with state terminology and not intended to make substantive changes to the content. For example, the federal regulations incorporated by reference refer to the "EPA" because it is the implementing agency. Yet, Arizona is authorized to implement and enforce the RCRA program contained in the incorporated regulations; therefore "EPA" is usually replaced with "ADEQ" when referring to the agency that implements the regulations. Because the changes to the federal regulations are generally to tailor the language to ADEQ, the changes to the incorporated text are not intended to have any additional impact beyond the federal regulation.

B. Descriptions of the revisions incorporated by reference.

1. Rule Title: Hazardous Waste Management: Liquids in Landfills. On November 18, 1992, EPA promulgated a final rule on liquids in landfills. That rule satisfied a statutory requirement in RCRA regarding the landfill disposal of containerized liquids. Specifically, the statute required EPA to issue a rule that prohibited the disposal in hazardous waste landfills of liquids that have been absorbed in materials that biodegrade. The November 18, 1992, rule includes 2 tests that could be used to demonstrate non-biodegradability. Today's rulemaking, which is issued in response to a petition, provides increased flexibility to the regulated community by adding another test to demonstrate that a sorbent is non-biodegradable. This rule can be found in Volume 60 of the Federal Register, page 35703, dated July 11, 1995.
2. Rule Title: RCRA Expanded Public Participation. This rule will improve the process for permitting facilities that store, treat, or dispose of hazardous wastes by providing earlier opportunities for public involvement in the process, and expanding public access to information throughout the permitting process and operational lives of the facilities. This rule can be found in 60 Fed. Reg. 63417, dated December 11, 1995.
3. Rule Title: Hazardous Waste Treatment, Storage, and Disposal Facilities and Hazardous Waste Generators: Organic Air Emissions Standards for Tanks, Surface Impoundments and Containers. This rule makes clarifying amendments in the regulatory text of final organic air emissions standards for tanks, surface impoundments, and containers. It also corrects typographical and grammatical errors and clarifies certain language in the preamble to the final rule published on December 6, 1994. This rule can be found in 61 Fed. Reg. 59932, dated November 25, 1996.
4. Rule Title: Identification and Listing of Hazardous Waste: Amendments to Definition of Solid Waste. This rule corrects the text of a regulatory exclusion from the regulatory definition of solid waste from recovered oil which is inserted into the petroleum refining process. The current text of the exclusion contains a factual error as to the location in the refining process at which recovered oil can be inserted. The result of this error is to inappropriately restrict legitimate recycling of recovered oil. The corrected rule also, in fact, reflects the result EPA initially intended, which was to condition the exclusion of recovered oil on the oil being reinserted into the petroleum refining process at a point where that process removes or will remove at least some contaminants. This rule can be found in 61 Fed. Reg. 13103, dated March 26, 1996.
5. Rule Title: Imports and Exports of Hazardous Waste: Implementation of OECD Council Decision C(92)39 Concerning the Control of Transfrontier Movements of Wastes Destined for Recovery Operations. This rule identifies the wastes, under RCRA, that are subject to a graduated system (green, amber, red) of procedural and substantive controls when

they move across national borders within the Organization for Economic Cooperation and Development (OECD) for recovery. It seeks to make the transaction fully transparent and to prevent or minimize the possibility of such wastes being abandoned or otherwise illegally handled. These requirements will apply only to U.S. exporters and importers of RCRA hazardous wastes destined for recovery in OECD countries (except for Canada and Mexico; waste shipments to and from these countries will continue to move under the current bilateral agreements and regulations). Those U.S. exporters and importers transacting hazardous waste movements outside the scope of today's rule will remain subject to EPA's current waste export and import regulations at 40 CFR 262, Subparts E and F. This rule does not increase the scope of wastes subject to U.S. export and import controls; it does, however, modify the procedural controls governing their export and import when shipped for recovery among OECD countries. Today's rule will remain subject to EPA's current waste export and import regulations at 40 CFR 262, Subparts E and F. This rule can be found in 61 Fed. Reg. 16290, dated April 12, 1996.

6. Rule Title: Land Disposal Restrictions Phase III -- Decharacterized Wastewaters, Carbamate Wastes, and Spent Potliners. This rule promulgates treatment standards for hazardous wastes from the production of carbamate pesticides and from primary aluminum production under the Land Disposal Restrictions (LDR) program. The purpose of the LDR program, authorized under RCRA, is to minimize short- and long-term threats to human health and the environment due to land disposal of hazardous waste. This rule is also amending the treatment standards for hazardous wastes that exhibit the characteristic of reactivity. These wastes are sometimes treated in lagoons whose ultimate discharge is regulated under the Clean Water Act, and sometimes injected into deep wells which are regulated under the Safe Drinking Water Act. Prior to today's rule, the treatment standard for these wastes required only removal of the characteristic property. The revised treatment standards require treatment, not only to remove the characteristic but also to treat any underlying hazardous constituents which may be present in the wastes. Therefore, these revised treatment standards will minimize threats from exposure to hazardous constituents which may migrate from lagoons or wells. Finally, this rule codifies as a rule EPA's existing Enforcement Policy that combustion of inorganic wastes is an impermissible form of treatment because hazardous constituents are being diluted rather than effectively treated. This rule can be found in 61 Fed. Reg. 15566, dated April 8, 1996; 61 Fed. Reg. 43924, dated August 26, 1996; and 62 Fed. Reg. 7502, dated February 19, 1997.
7. Rule Title: Land Disposal Restrictions Phase III -- Decharacterized Wastewaters, Carbamate Wastes, and Spent Potliners. In 61 Fed. Reg. 15566 (see Item 6 above), EPA promulgated a final rule which, among other things, revises treatment standards for hazardous wastewaters that exhibit the characteristic of ignitability, corrosivity, or toxicity. The revised treatment standards were promulgated to implement the mandate of the opinion of the Circuit Court of Appeals for the District of Columbia Circuit in *Chemical Waste Management (CWM) v. EPA*, 976 F.2d 2 (D.C. Cir. 1992) cert. denied 507 U.S. 1057 (1993). On March 26, 1996, President Clinton signed into law the Land Disposal Program Flexibility Act of 1996, which, among other things, provides that the wastes in question are no longer prohibited from land-disposal so long as they are not hazardous wastes at the point they are land-disposed. By operation of the statute, this provision is made effective immediately and, therefore, essentially overrules this portion of the *CWM v. EPA* opinion. This rule, accordingly, is incorporating the statutory provision into the regulations by amending or withdrawing the portions of the regulations that are superseded by the new legislation. The amendment/withdrawal of these standards does not affect any other part of the final rule; and the effective dates of the other actions in the final rule likewise will not change. Furthermore, this rule amends parts of the LDR Phase II final rule, published on September 19, 1994 (59 Fed. Reg. 47982) which are also overruled by the legislation. This regulation can be found in 61 Fed. Reg. 15660, dated April 8, 1996.
8. Rule Title: Land Disposal Restrictions Phase III -- Decharacterized Wastewaters, Carbamate Wastes, and Spent Potliners. This rule corrects several effective dates in 61 Fed. Reg. 15566 (see Item 6 above) This regulation can be found in 61 Fed. Reg. 19117, dated April 30, 1996.
9. Rule Title: Land Disposal Restrictions Phase III -- Decharacterized Wastewaters, Carbamate Wastes, and Spent Potliners. This rule corrects technical errors in 61 Fed. Reg. 15566 (see Item 6 above). This rule can be found in 61 Fed. Reg. 33680, dated June 28, 1996.
10. Rule Title: Land Disposal Restrictions Phase III -- Decharacterized Wastewaters, Carbamate Wastes, and Spent Potliners. This rule corrects typographical errors in 61 Fed. Reg. 15566 (see Item 6 above). This rule can be found in 61 Fed. Reg. 36419, dated July 10, 1996.
11. Rule Title: Criteria for Classification of Solid Waste Disposal Facilities and Practices; Identification and Listing of Hazardous Waste; Requirements for Authorization of State Hazardous Waste Programs. This rule revises the existing criteria for solid waste disposal facilities and practices. The revisions in this rule establish that only those non-municipal non-hazardous waste disposal units that meet specific standards may receive conditionally exempt, small-quantity generator (CESQG) hazardous wastes. These revisions establish standards pertaining to location restrictions, groundwater monitoring, and corrective action. EPA is also finalizing revisions to regulations for hazardous wastes generated by CESQGs. The language in this rule clarifies acceptable disposal options under Subtitle D of RCRA by specifying that CESQG hazardous waste may be managed at municipal solid waste landfills subject to § 258 and at non-municipal, non-hazardous waste disposal units subject to the revised criteria. This rule can be found in 61 Fed. Reg. 34251, dated July 1, 1996.

C. Summary of state-specific changes.

1. In order to comply with the provisions of A.R.S. § 49-922(A) which states: "The director shall not adopt a nonprocedural standard that is more stringent than or conflicts with those found in 40 CFR sections 260 through 268, 270 through 272 and 124," ADEQ is proposing to recognize and enforce variances granted by the EPA pursuant to 40 CFR 260.30 - 260.33. These provisions pertain to variances from classification of certain recycled materials as solid waste and variances to be classified as a boiler of certain closed devices using controlled-flame combustion. By previously excluding the variance process completely from rule, ADEQ prevented anyone from obtaining a variance. Because of the many complex scientific, technical, manufacturing processes and economic issues involved, ADEQ believes the expertise for determining whether a variance should be granted/denied is better placed with the EPA. For this reason, ADEQ is not incorporating 40 CFR 260.30 - 260.33 by reference; instead these paragraphs are replaced in R18-8-260(J) and (K) by language expressly stating that when the EPA Administrator grants the variance, the Director shall accept such determination, provided the variance is consistent with the policies and purposes of the HWMA.
2. ADEQ is proposing to add clarifying language to R18-8-260 for a small- or large-quantity generator for the annual registration fee. ARS § 49-929 defines small- and large-quantity hazardous waste generators based upon a "per month" amount of hazardous waste generated. The "per month" can be interpreted as an average amount per month averaged over a year period, or the actual amount generated in any month in the calendar year. Therefore, the proposed rule expressly states in R18-8-260(M) that, for the annual registration fee purposes, hazardous waste generator status is determined by the amount of hazardous waste generated in any month of the prior year.
3. ADEQ is proposing to amend R18-8-262(I) and (J) to expressly state the time-frame for submission of the exception report. This is intended to clarify a vague area of the rule.
4. ADEQ is proposing changes to R18-8-273 by adding subsections(A) through (J). These changes will allow mercury-containing waste lamps to be designated as a universal waste and allow management of mercury-containing lamps as a universal waste. Nearly every business, institution, and government agency, as well as many households, generate thousands of waste lamps that could become a hazardous waste problem if not handled properly. If these lamps are burned or disposed of in landfills, the mercury in them can be released into the environment. Based on EPA-performed tests on a broad range of waste lamps, the mercury-containing lamps such as fluorescent lamps will most probably fail the toxicity characteristic leaching procedure limit.

ADEQ believes that allowing mercury-containing waste lamps to be managed as a universal waste will greatly facilitate environmentally sound collection and increase the proper recycling or treatment of mercury-containing waste lamps. The risk posed by mercury-containing lamps during accumulation and transport is relatively low (for example, similar to mercury-containing thermostats which are already classified as a universal waste in 40 CFR 273) compared to other hazardous wastes. The proposed management standards are protective of human health and the environment while substantially easing the existing hazardous waste management requirements.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

8. The summary of the economic, small business, and consumer impact:

A. Identification of adopted rulemaking

This rulemaking, known as the 1995-96 amendments to the hazardous waste rules, incorporates changes in federal regulations that were promulgated between July 2, 1995, and July 1, 1996. This rulemaking also includes state-specific changes. It is codified in 18 A.A.C. 8, Article 2 (Department of Environmental Quality - Waste Management: Hazardous Wastes, R18-8-260 - R18-8-273).

This section contains a summary of ADEQ's final EIS developed for this rulemaking. A copy of the full EIS may be obtained by contacting David Lillie, ADEQ, 3033 North Central Avenue #844, Phoenix, Arizona 85012, or by telephone at (602) 207-4436, or toll-free within Arizona at (800) 234-5677, extension 4436.

B. Introduction

The primary purpose for amending these rules is to incorporate the text of federal regulations that have changed. This is necessary for ADEQ to maintain EPA authorization to administer the federal hazardous waste program in Arizona in lieu of EPA. Incorporating these changes into Arizona's program will not represent an incremental cost because these changes already are effective, except for expanded public participation. Expanded public participation is expected to generate minimal costs to regulated industry (refer to "C" below).

In addition to these federal changes, which include minor corrections, ADEQ is making certain state-specific changes. Although these state changes include language clarification, the most important provisions are these: ADEQ can accept EPA-granted variances, and ADEQ can designate mercury-containing waste lamps as a universal waste, which means less stringent management options will apply. These changes are deregulatory, representing a potential cost-savings to regulated industry (refer to "C" below).

Potential classes of persons affected by this rulemaking include: generators, treatment, storage, and disposal (TSD) facilities, transporters, mercury-containing waste lamp storing or recycling facilities, ADEQ (implementing agency), and the public.

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The current database of generators includes 900 small-quantity generators (SQGs), 200 large-quantity generators (LQGs), and 1,200 conditionally exempt SQGs (CESQGs). However, this rulemaking is not expected to impact most, if any, CESQGs. There also are 39 TSD facilities operating in Arizona. Note that while individual households may, at their option, manage mercury-containing waste lamps as a universal waste, they do not have to do so under this rulemaking.

Classes of persons will be affected in varying degrees both within the classes and from 1 class to another. Although benefits may accrue to regulated industry in terms of cost-savings, the public also is expected to benefit from improved protection of human health and the environment. ADEQ is expected to benefit from improvements to its hazardous waste program. Consumers could be affected from higher public participation costs which may be passed on to them, but ADEQ believes these costs, if any, will be de minimis. ADEQ concludes that probable benefits will outweigh probable costs of this rulemaking.

C. Potential Impacts on Regulated Industry

ADEQ concluded that this rulemaking will impact the following regulated industries: (1) Treatment, storage, and disposal (TSD) facilities involved in expanded public participation; (2) Generators and TSD facilities involved in petitioning EPA for a variance; and (3) Generators, TSD facilities, and transporters involved in the management of mercury-containing waste lamps. These impacts are summarized below:

1. The expanded public participation provision provides for earlier public involvement in the permitting process and expanded public access to information during the permitting process and the operation of the facility. ADEQ expects an average of only 1 TSD facility per year will need to comply with this new provision. The compliance burden (real-resource costs) is estimated to range \$5,000-14,000 per facility (if not required to do a trial burn). If the facility must perform a trial burn, the cost to the facility will be an additional \$2,000.
2. The variance provision enables ADEQ to accept a variance granted by EPA (from classification as a solid waste or a boiler). Currently, there is no mechanism for a facility to receive a variance by petitioning either EPA or ADEQ. It is unknown how many facilities will petition EPA for a variance. This provision is classified as deregulatory because it could represent a cost-savings to regulated industry. ADEQ cannot monetize the cost-savings impact of this provision.
3. The change of regulating mercury-containing waste lamps as a universal waste provides for less stringent management options. Currently, this waste is managed with the full RCRA Subtitle C waste management requirements. Because this change will ease the regulatory burden of collecting and transporting this waste, this rule provision is classified as deregulatory because it represents a potential cost-savings to regulated industry. ADEQ cannot monetize the cost-savings impact of this provision. However, EPA estimated that cost-savings could average \$300 per generator or, expressed in other terms, 5¢ per waste lamp; actual savings will vary according to site-specific factors.

In the future, after this rulemaking is effective, actual benefits may be monetized by some entities, but for others it may not be possible to quantify or monetize potential benefits. However, some expected benefits could include: reduced permitting costs and quicker start-up schedules due to potential savings from improved communication and avoided delays (from public controversy and litigation); reduced operation costs due to the granting of variances from classifications as a solid waste or a boiler; reduced handling, storing, and hauling costs of mercury-containing waste lamps due to less stringent management options; and other business savings due to the improved efficiency and effectiveness of the hazardous waste program (from rule clarifications and corrections and improved flexibility).

D. Social Impacts

This rulemaking is expected to have a very minimal social cost. This is because compliance by the regulated industry will not result in any deadweight-welfare losses, adjustment costs for displaced resources, or other business and/or market costs. Because ADEQ does not anticipate any type of reduction in industry output, deadweight-welfare losses are expected to be zero, that is, because no net losses in consumers' and producers' surplus are anticipated. Furthermore, real-resource costs (for example, direct and indirect costs, compliance costs, and administrative costs) to regulated industry are expected to be minimal. Finally, this rulemaking will not have an impact on state revenues.

The social cost to society (mainly Arizona residents) due to ADEQ promulgating this rule, principally is comprised of real-resource costs incurred by the regulated community to comply with expanded public participation (\$5,000 - \$14,000 per facility). Other social costs include costs that will be incurred by ADEQ (implementing agency). They include future regulatory costs associated with this rulemaking, but they are expected to be minimal. Rule development costs should not be included in an EIS because they represent sunk costs once a rulemaking is effective.

In the future, after this rulemaking is effective, actual social benefits may be monetized by some entities, but for others it may not be possible to quantify or monetize any potential benefits. Nevertheless, ADEQ expects both direct and indirect social benefits to accrue as a result of cost-saving potentials. For example, rule clarification should increase hazardous waste program efficiency. Managing mercury-containing waste lamps as a universal waste with less stringent management requirements could encourage recycling and proper treating of these waste lamps. Enhancing the effectiveness of public participation has the potential to do all of the following: streamline the permitting process; improve environmental justice; empower the public to become more involved in the permitting process and facility operation; and foster communication and mutual understanding. Thus, as a result of these potential benefits, ADEQ expects to improve the effectiveness of Arizona's hazardous waste program. This has the potential to improve the protection of human health and the environment which is expected to have a positive social impact.

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E. Anticipated Impacts on Employment, Revenues, and Expenditures

This rulemaking is not expected to impact short- or even long-run employment, production, or industrial growth in any fashion. This conclusion applies to both private and public sectors. ADEQ expects no facility closures, no reductions in output, no increases or decreases in employment, nor any reemployment or other transitional employment problems. More specifically, ADEQ expects no shifts in demand or price for mercury-containing lamps. Furthermore, ADEQ expects no immediate-appreciable impact on employment, revenues, or expenditures of transporters of mercury-containing waste lamps and owners/operators of storage or recycling facilities. Finally, because of the nature of this rulemaking, secondary economic effects on employment and other factors (for example, city, town, and regional areas, energy, capital availability, and trade), whether they are likely or not to exist, have not been considered in this EIS, except for an explanation about potential indirect impacts on energy consumption and pollution.

With a reduced regulatory structure of handling these waste lamps, non-hazardous waste transporters could haul them. Generators or TSD facilities could haul this waste at a cost-savings to them, or either hazardous or non-hazardous transporters could haul this waste at a competitive cost. Most likely, the hazardous waste transporter would have to reduce its rate to be competitive with the non-hazardous transporter. Obviously, transporters could pass-on savings to their customers.

ADEQ expects that any administrative burden arising from this rulemaking (for example, mainly due to expanded public participation requirements) can be effectively handled by its current personnel. Thus, no additional FTEs will be required. In all instances, ADEQ will pass on this notification burden to the applicant in the final fee charged.

F. General Impact on Small Businesses and Reduction of Impacts

Although ADEQ data do not identify facilities classified as small businesses, hazardous waste program staff estimate 80-90% of the 900 SQGs and 90% of the 1,200 CESQGs would be small businesses. Unlike the other generators, only a small proportion of the 200 LQGs and probably none of the 39 TSD facilities would be considered small businesses. As a result of this apportionment, approximately 80% of the 2,339 generators would be classified as small businesses. However, ADEQ believes the majority, by far, will be unaffected by this rulemaking (particularly the 1,200 CESQGs).

In addition, ADEQ staff identified that approximately 60 SQGs, 70 CESQGs, 20 LQGs, and 10 TSD facilities represent government entities, including schools. ADEQ believes that either none of these government entities will be impacted or some of them will be impacted positively, even though some TSD facilities in Arizona may incur additional costs for expanded public participation.

ADEQ is sensitive to the concerns of small businesses and the impact this rulemaking would have upon them. Accordingly, prior to proposing this rulemaking, ADEQ considered each of the 5 methods prescribed in A.R.S. § 41-1035 for reducing the impact on small businesses. Likewise, ADEQ considered each of the 3 methods prescribed in A.R.S. § 41-1055(B)(5)(c). The result was that ADEQ could not provide additional regulatory relief for small businesses beyond what was built-in by federal requirements or the deregulatory aspects of federal and state standards.

Because this rulemaking predominantly will result in a reduction in regulation (previously referred to as deregulatory), the only possible cost that small businesses would incur would be due to expanded public participation provisions. Most importantly, this provision only applies to TSD facilities, which currently number 39.

ADEQ has no authority to exempt a small business, or even establish a less stringent standard or schedule for it, or any business as a matter of fact, from compliance or reporting requirements. Pursuant to A.R.S. § 49-922(A), ADEQ's hazardous waste program must be "equivalent to and consistent with" federal hazardous waste regulations. In addition, ADEQ's non-procedural program standards must not be more stringent than or conflict with federal regulations. Under these conditions, ADEQ cannot provide additional relief to small businesses because it would not be legal or feasible. If ADEQ deviated from these rulemaking provisions, it would jeopardize EPA authorization to administer the federal hazardous waste program in Arizona, which, in addition to other negative impacts, would mean a loss of approximately \$1.5 million annually.

G. Alternative Rulemaking Provisions

ADEQ could not find any less costly or less intrusive rule provisions of achieving the goals and objectives of this rulemaking. The reason is that most of these changes, which are incorporated by reference, either do not constitute incremental impacts or they are deregulatory. Refer to the discussion above.

9. A description of the changes between the proposed rules, including supplemental notices, and final rules:

EPA has notified ADEQ that the incorporation by reference for the public participation rule posed an adoption problem of 40 CFR 124 because of a sentence in this regulation that limits EPA's permit issuance authority. This could create a problem when a state incorporates the federal regulation by reference because a blanket substitution that replaces EPA with the state agency creates a limitation on the state's permitting authority. This does not make sense and was not intended by the rule. The following subsections were added to R18-8-271 to remedy the problem stated above:

R. §124.31(a) entitled "Pre-application public meeting and notice" is amended by deleting the following sentence:

"For the purpose of this section only, 'hazardous waste management units over which EPA has permit issuance authority' refers to hazardous waste management units for which the State where the units are located has not been authorized to issue RCRA permits pursuant to 40 CFR 271."

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- S. §124.32(a) entitled "Public notice requirements at the application stage" is amended by deleting the following sentence:

"For the purpose of this section only, 'hazardous waste management units over which EPA has permit issuance authority' refers to hazardous waste management units for which the State where the units are located has not been authorized to issue RCRA permits pursuant to 40 CFR 271."

- T. §124.33(a) entitled "Information repository" is amended by deleting the following sentence:

"For the purpose of this section only, 'hazardous waste management units over which EPA has permit issuance authority' refers to hazardous waste management units for which the State where the units are located has not been authorized to issue RCRA permits pursuant to 40 CFR 271."

After the proposal of this rule package, EPA clarified an issue concerning the rule entitled: "Imports and Exports of Hazardous Waste: Implementation of OECD Council Decision C(92)39 Concerning the Control of Transfrontier Movements of Wastes Destined for Recovery Operations" (see explanation of this rule in preamble, question #5). Like the requirements at 40 CFR 262, Subparts E and F previously incorporated by reference by Arizona, the requirements at 40 CFR 262, Subpart H (which is the OECD provision) will be administered by EPA and not the states because the exercise of foreign relations and international commerce powers are reserved to the Federal Government under the Constitution. Therefore, R18-8-260(E) and (F) dealing with definitions must be changed as shown below to preclude any references to "EPA" or "Administrator" from being changed to "ADEQ" or "the Director" in the effected sections of 40 CFR 262, 264 and 265:

- E. § 260.10, entitled "Definitions", is amended by adding all definitions from § 270.2 to this section (as incorporated by R18-8-260 and R18-8-270), including the following changes, applicable throughout this Article unless specified otherwise:

1. Through 11. No Change

12. ["EPA", "Environmental Protection Agency", "United States Environmental Protection Agency", "U.S. EPA", "EPA HQ", "EPA Regions", and "Agency" mean the DEQ with the following exceptions:

- a. Any references to EPA identification numbers;
- b. Any references to EPA hazardous waste numbers;
- c. Any reference to EPA test methods or documents;
- e. Any reference to EPA publications;
- f. Any reference to EPA manuals;
- g. Any reference to EPA guidance;
- h. Any reference to EPA Acknowledgment of Consent;
- i. References in §§ 260.2(b) (as incorporated by R18-8-260(D)(2));
260.10 (definitions of "Administrator", "EPA region", "Federal agency", "Person", and "Regional Administrator" (as incorporated by R18-8-260(E));
260, Appendix I (as incorporated by R18-8-260(C));
260.11(a) (as incorporated by R18-8-260);
261, Appendix IX (as incorporated by R18-8-261(A));
262.32(b) (as incorporated by R18-8-262(A));
262.50 through 262.57 (as incorporated by R18-8-262(A));
262.80 through 262.89 (as incorporated by R18-8-262(A));
262, Appendix (as incorporated by R18-8-262(A));
263.10(a) Note (as incorporated by R18-8-263(A));
§§ 264.12(a)(2), 264.71(d), 265.12(a)(2), 265.71(d);
268.1(e)(3) (as incorporated by R18-8-268);
268.5, 268.6, 268.42(b), and 268.44), which are nondelegable to the state of Arizona (as incorporated by R18-8-268); 270.1(a)(1) (as incorporated by R18-8-270);
270.1(b) (as incorporated by R18-8-270(B));
270.2 (definitions of "Administrator", "Approved program or Approved state", "Director", "Environmental Protection Agency", "EPA", "Final authorization", "Permit", "Person", "Regional Administrator", and "State/EPA agreement") (as incorporated by R18-8-270(A));
270.3 (as incorporated by R18-8-270(A));
270.5 (as incorporated by R18-8-270(A));
270.10(e)(1) through (2) (as incorporated by R18-8-270(A) and R18-8-270(D));
270.11(a)(3) (as incorporated by R18-8-270(A));
270.32(a) and (c) (as incorporated by R18-8-270(M) and R18-8-270(O));
270.51 (as incorporated by R18-8-270(P));
270.72(a)(5) and (b)(5) (as incorporated by R18-8-270(A));

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124.1(f) (as incorporated by R18-8-271(B));
124.5(d) (as incorporated by R18-8-271(D));
124.6(e) (as incorporated by R18-8-271(E));
124.10(c)(1)(ii) (as incorporated by R18-8-271(I)); and
124.13 (as incorporated by R18-8-271(L)).]

13. through 32. No Change

- F. § 260.10, entitled "Definitions", as amended by subsection (E) also is amended as follows, with all definitions in § 260.10 (as incorporated by R18-8-260), applicable throughout this Article unless specified otherwise.

1. "Act" or ["the Act" means the state Hazardous Waste Management Act or HWMA, except in R18-8-261(B) and R18-8-262(B).]
2. "Administrator", "Regional Administrator", "state Director", or "Assistant Administrator for Solid Waste and Emergency Response" mean the [Director or the Director's authorized representative, except in §§ 260.10, definitions of "Administrator", "Regional Administrator", and "hazardous waste constituent" (as incorporated by R18-8-260(E));

261, Appendix IX (as incorporated by R18-8-261(A));

262, Subpart E;

262, Subpart H;

262, Appendix (as incorporated by R18-8-262);

264.12(a) (as incorporated by R18-8-264(A));

265.12(a) (as incorporated by R18-8-265(A));

268.5, 268.6, 268.42(b), and 268.44, which are nondelegable to the state of Arizona (as incorporated by R18-8-268);

270.2, definitions of "Administrator", "Director", "Major facility", "Regional Administrator", and "State/EPA agreement" (as incorporated by R18-8-270(A));

270.3 (as incorporated by R18-8-270(A));

270.5 (as incorporated by R18-8-270(A));

270.10(e)(1), (2), and (4) (as incorporated by R18-8-270(A) and R18-8-270(D));

270.10(f) and (g) (as incorporated by R18-8-270(A) and R18-8-270(E));

270.11(a)(3) (as incorporated by R18-8-270(A));

270.14(b)(20) (as incorporated by R18-8-270(A));

270.32(b)(2) (as incorporated by R18-8-270(N));

270.51 (as incorporated by R18-8-270(A));

124.5(d) (as incorporated by R18-8-271(D));

124.6(e) (as incorporated by R18-8-271(E));

124.10(b) (as incorporated by R18-8-271(I));

3. Through 7. No Change

ADEQ in conjunction with the Governor's Regulatory Review Council (GRRC) staff determined that the following changes clarified new language and removed the "legalese" terminology.

R18-8-260 was amended as follows:

- J. § 260.30, entitled "Variances from classification as a solid waste," is replaced by the following: Any person wishing to submit a variance petition shall submit the petition, under this subsection, to the EPA. Where the administrator of EPA has granted a variance from classification as a solid waste pursuant to 40 CFR 260.30, 260.31 and 260.33, the director shall accept ~~such a~~ the determination, provided the director determines ~~such the~~ action is consistent with the policies and purposes of the HWMA.
- K. § 260.32, entitled "Variances to be classified as a boiler," is replaced by the following: Any person wishing to submit a variance petition shall submit the petition, under this subsection, to the EPA. Where the administrator of EPA has granted a variance from classification as a boiler pursuant to 40 CFR 260.32 and 260.33, the director shall accept ~~such the~~ determination, provided that the director determines ~~such the~~ action is consistent with the policies and purposes of the HWMA.
- L. No Change
- M. As required by A.R.S. § 49-929, generators and transporters of hazardous waste shall register annually with DEQ. ~~The application for registration shall be accompanied by a registration fee for any of the following applicable application and submit the appropriate registration fee, prescribed below, with their registration:~~

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1. A hazardous waste transporter that picks-up or delivers hazardous waste in Arizona ~~is required to~~ shall pay \$200 by March 1 of the year following the date of the pick-up or delivery.
2. A large-quantity generator which generated 1,000 kilograms or more of hazardous waste in any month of the previous calendar year ~~is required to~~ shall pay \$300.
3. A small-quantity generator which generated 100 kilograms or more but less than 1,000 kilograms of hazardous waste in any month of the previous year ~~is required to~~ shall pay \$100.

ADEQ in conjunction with the GRRC staff determined that the reader needed clarity on the incorporations by reference. Rather than stating "as amended at" for subsection (A) of each Section that incorporates by reference, this phrase was replaced with "in". R18-8-261(A) is shown below with the change that is made in each subsection (A) of each Section.

- A. All of 40 CFR 261 and accompanying appendices, as amended as of July 1, 1966 (and no future editions), with the exception of § 261.5(j), are incorporated by reference and modified by the following subsections of R18-8-261 and are on file with the DEQ and the Office of the Secretary of State. In addition, all amendments to Part 261 and its appendices ~~as amended at in~~ 61 Fed. Reg. 59932, on November 25, 1996, are incorporated by reference and on file with the DEQ and the Office of Secretary of State.

ADEQ in conjunction with GRRC staff determined that the following changes were necessary for clarity and grammatically correct statements.

R18-8-273 was amended as follows:

- C. Applicability-mercury-containing lamps. ~~Mercury-containing lamps as described in R18-8-273.~~ The requirements of this section apply to persons managing mercury-containing lamps as described in subsection (D) of this Section, except those listed in subsection (C)(1).
 1. No Change
 - a. No Change
 - b. No Change
 2. No Change
 - a. No Change
 - b. No Change
- D. § 273.6, entitled "Definitions" is amended by adding the following definition: "Mercury-containing lamp" means the bulb or tube portion of a lighting device specifically designed to produce radiant energy, most often in the ultra-violet (UV), visible, and infrared (IR) regions of the electromagnetic spectrum. Four common mercury containing lamps are fluorescent lamps, sodium-vapor lamps, high- and low-pressure mercury vapor lamps, and high intensity discharge (HID) lamps.
- E. No Change
- F. § 273.13, entitled "Waste management" is amended by adding paragraph (d) as follows:
 - (d) Universal waste lamps. A small-quantity handler of universal waste shall manage universal waste lamps in a way that prevents releases of any universal waste or component of any universal waste to the environment, as follows:
 - (1) A small-quantity handler shall manage universal waste lamps in a way that minimizes lamp breakage. ~~The small-quantity handler shall:~~
 - (i) ~~Contain contain~~ unbroken lamps in packaging that will minimize breakage during normal handling; and
 - (ii) ~~Contain contain~~ broken lamps in packaging that will minimize releases of lamp fragments and residues.
 - (2) A small-quantity handler of universal waste lamps shall immediately contain all releases of residues from hazardous waste lamps.
 - (3) A small-quantity handler of universal waste lamps shall determine whether any materials (i.e., mercury, residues, or other solid wastes) resulting from the release exhibit a characteristic of hazardous waste, and if so, shall manage the waste in accordance with all applicable requirements in 40 CFR §§ 260 through 272 (as incorporated by R18-8-260 through R18-8-271).
 - (4) If the mercury, residues, or other solid waste is not hazardous, the handler may manage the waste in any way that is in compliance with applicable federal, state or local solid waste regulations.
- E. No Change
- F. No Change
- G. No Change

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H. § 273.33, entitled "Waste management" is amended by adding paragraph (d) as follows:"

- (d) Universal waste lamps. A large-quantity handler of universal waste shall manage universal waste lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:
- (1) A large-quantity handler shall manage universal waste lamps in a way that minimizes lamp breakage. ~~The large-quantity handler shall:~~
 - (i) ~~Contain contain~~ unbroken lamps in packaging that will minimize breakage during normal handling; and
 - (ii) ~~Contain contain~~ broken lamps in packaging that will minimize releases of fragments and residues.
 - (2) A large-quantity handler of universal lamps shall immediately contain all releases of residues from hazardous waste lamps.
 - (3) A large-quantity handler of universal waste lamps shall determine whether any materials (that is, mercury, residues, or other solid wastes) resulting from the release exhibit a characteristic of hazardous waste, and if so, shall manage the waste in accordance with all applicable requirements in 40 CFR 260 through 272 (as incorporated by R18-8-260 through R18-8-271).
 - (4) If the mercury, residues, or other solid waste is not hazardous, the handler may manage the waste in any way that is in compliance with applicable federal, state or local solid waste regulations.

ADEQ and GRRC staff determined that R18-8-260(G) and (H) were missing an amendment contained in the Federal Register that was incorporated by reference. R18-8-261(G) and (H) were amended to incorporate paragraphs (iv) and (v) of 40 CFR 261 as shown below:

- (iv) Permitted, licensed, or registered by a state to manage municipal [or industrial solid waste [and approved by the owner or operator of the solid waste facility to accept acute hazardous waste from conditionally exempt small quantity generators that have not been excluded from disposing of their waste at such a facility pursuant to applicable provisions of the Solid Waste Management Act, A.R.S. §§ 49-701 through 49-791 and] is subject to Part 258 of this Chapter;
- (v) Permitted, licensed, or registered by a state to manage non-municipal non-hazardous waste and, if managed in a non-municipal non-hazardous waste disposal unit after January 1, 1998, is subject to the requirements in §§257.5 through 257.30 of this chapter; or

10. A summary of the principal comments and the agency response to them:

There were no comments made at the oral proceeding or received by mail during the comment period. The following comments were received prior to proposal of the rule and are listed to explain the agency's consideration of those comments.

Comment: Two commenters requested during the informal process that ADEQ allow generators under the universal waste standards to crush mercury-containing waste lamps as a management practice in well-controlled crushers such as the Dextrite crusher.

Agency's Response: ADEQ understands the desire of generators of mercury-containing waste lamps to be able to crush these waste lamps for the purpose of volume reduction. However, there are some issues that must be clarified before crushing at the generator, transporter, and accumulation points are contemplated. First, mercury is a highly toxic heavy metal and is volatile at room temperature; therefore it is very important that no release of mercury vapors occurs during the crushing process. While ADEQ recognizes that well-controlled portable crusher systems that mount on top of a barrel, usually a 55-gallon drum, are available, their reliability is not yet fully known. These crushers employ activated charcoal filters to trap the mercury vapors, and their saturation point depends on the amount of mercury passing through them which, in turn, varies with the ambient temperature; therefore, the actual effective filtration time may vary significantly under different climatic conditions, making a release a real possibility. Second, it appears inconsistent to relax the requirement of 40 CFR 260 through 272 for generators who crush and accumulate crushed mercury-containing waste lamps in portable crushers while the destination facilities that treat, store, and recycle mercury-containing waste lamps in large permanent facilities, more stringently designed to minimize the possibilities of a release to the atmosphere than the small portable crushers, are required to comply with all requirements of 40 CFR 260 through 272. Third, given that the crushed mercury-containing waste lamps exhibit the characteristic of toxicity, and the fact that mercury is high on the scale of human health and ecological risk potential, it appears reasonable, in the absence of data to the contrary, to subject such waste to the full hazardous waste management requirements of RCRA Subtitle C.

ADEQ, by adopting a rule to include mercury-containing waste lamps as universal waste, is leading EPA in this effort. But, given the technical uncertainties, ADEQ prefers to wait for EPA's final determination, which will be based on public comments, expert contractor analyses, and risk assessments, before making a final decision on whether to allow crushed lamps to be managed as universal waste in Arizona. EPA's determination on how best to manage mercury-containing waste lamps is scheduled to be released late this year or early next year.

Comment: Some commenters believe that, due to the fragile nature of mercury-containing waste lamps, a handler taking appropriate measures to avoid lamp breakage will still have some breakage. The commenters requested that ADEQ allow "incidental" breakage to be subject to the universal waste management practices.

Agency's Response: The amount of mercury released from a broken mercury-containing waste lamp varies with ambient air temperature, the length of time the broken lamps are directly exposed to the air, and the number of lamps broken. As a result, the risk of handling the broken lamps in accordance with streamlined universal waste management practices are unknown at this time.

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EPA in 59 Fed. Reg. 38283, dated July 27, 1994, also states that the Agency recognizes that it is uncertain how much mercury is released from broken mercury-containing waste lamps. The Agency further requests any available data concerning releases of mercury during storage, transportation, and waste management activities. In view of the above, and until EPA reviews and releases all information and their determination on this topic, ADEQ believes that the most responsible manner in which to handle lamp breakage is to immediately contain all spills or releases of mercury and, if the residues or other solid waste exhibit a characteristic of hazardous waste, then manage it in compliance with all applicable portions of 40 CFR 260 through 272. This issue will be revisited when expert data becomes available.

Comment: Under R18-8-273(J), a destination facility shall submit a Part A and B application within 180 days of the effective date of the rule. One commenter requested that, to encourage recycling of mercury-containing waste lamps, ADEQ allow on-site storage at the recycling facility for a period not to exceed 10 days.

Agency's Response: ADEQ's intent in proposing to include mercury-containing waste lamps as a universal waste is to encourage sound collection, transportation, and recycling of this waste stream. However, the rule is not intended to provide a new exemption for recyclers that also store mercury-containing waste lamps prior to recycling.

In an issue unrelated to universal waste management, but 1 that would also benefit universal waste recyclers, ADEQ is considering proposing a change to 40 CFR 261.6(c). Under this change owners or operators of facilities that store recyclable materials for 10 days or less before they are recycled would not have to be permitted provided certain provisions are complied with. If the proposed changes, after receiving a thorough public hearing, are adopted through the rulemaking process, the end result is expected to accomplish the commenters intent. Most likely this rule will be promulgated as part of the 1996-1997 rule package.

Comment: One individual inquired about the permit described in R18-8-273(J), for recycling mercury-containing waste lamps. The individual questioned how this differed from an ADEQ compliance agreement which did not require the mercury-containing waste lamp processing/recycling facility to obtain a permit.

Agency's Response: The compliance agreement the inquirer asked about was issued temporarily to enable destination facilities (processors/recyclers of mercury-containing waste lamps) to commence operating in Arizona until the rule to include mercury-containing waste lamps as universal waste is promulgated. Once this rule becomes effective, all destination facilities that process mercury-containing waste lamps will be subject to Subpart E of 40 CFR 273, "Standards for Destination Facilities," which includes permitting.

Comment: ADEQ received positive feedback from a couple of the mercury-containing waste lamp recyclers. They stated that the incorporation of the mercury-containing waste lamp recyclers will simplify their ability to collect from more small-quantity generators and that overall this rule will benefit the recycler and the recycling process.

Agency's Response: While we agree that this rule will benefit the recyclers of mercury-containing waste lamps, we also believe that this rule will benefit the collectors (accumulation points), transporters, and generators of universal waste by reducing reporting and recordkeeping requirements and streamlining the overall management system for these wastes.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable.

12. Incorporations by reference and their location in the rules:

| | | |
|------------|---------------------------------|-----------|
| 40 CFR 260 | | R18-8-260 |
| 40 CFR 261 | Including 61 FR 59932, 11/25/96 | R18-8-261 |
| 40 CFR 262 | Including 61 FR 59932, 11/25/96 | R18-8-262 |
| 40 CFR 263 | | R18-8-263 |
| 40 CFR 264 | Including 61 FR 59932, 11/25/96 | R18-8-264 |
| 40 CFR 265 | Including 61 FR 59932, 11/25/96 | R18-8-265 |
| 40 CFR 266 | | R18-8-266 |
| 40 CFR 268 | Including 61 FR 43924, 8/26/96 | R18-8-268 |
| | Including 61 FR 36419, 7/10/96 | |
| | Including 61 FR 7502, 2/19/97 | |
| 40 CFR 270 | Including 61 FR 59932, 11/25/96 | R18-8-270 |
| 40 CFR 124 | | R18-8-271 |
| 40 CFR 273 | | R18-8-273 |

13. Were these rules adopted as emergency rules?

No.

14. The full text of the rule follows:

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TITLE 18. ENVIRONMENTAL QUALITY

**CHAPTER 8. DEPARTMENT OF ENVIRONMENTAL QUALITY
WASTE MANAGEMENT**

ARTICLE 2. HAZARDOUS WASTES

Section

- R18-8-260. Hazardous Waste Management System: General
- R18-8-261. Identification and Listing of Hazardous Waste
- R18-8-262. Standards Applicable to Generators of Hazardous Waste
- R18-8-263. Standards Applicable to Transporters of Hazardous Waste
- R18-8-264. Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
- R18-8-265. Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
- R18-8-266. Standards for the Management of Specific Hazardous Wastes and Specific Hazardous Waste Management Facilities
- R18-8-268. Land Disposal Restrictions
- R18-8-270. The Hazardous Waste Permit Program
- R18-8-271. Procedures for Permit Administration
- R18-8-273. Standards for Universal Waste Management

- (2) No Change
- ii. No Change
 - (1) No Change
 - (2) No Change
- iii. No Change
 - (1) Change
 - (2) No Change
 - (3) No Change
 - (4) No Change
- f. No Change
 - i. No Change
 - ii. No Change
 - iii. No Change
 - iv. No Change
 - v. No Change

ARTICLE 2. HAZARDOUS WASTES

R18-8-260. Hazardous Waste Management System: General

- A. Federal and state statutes and regulations cited in these rules are those adopted as of July 1, 1995 1996, unless otherwise noted. 40 CFR 124, 260 through 266, 268, 270, and 273 or parts thereof, are adopted by reference when so noted. Federal statutes and regulations that are cited within 40 CFR 124 and 260 through 270 that are not adopted by reference may be used as guidance in interpreting federal regulatory language.
- B. No Change
- C. All of 40 CFR 260 and the accompanying appendix, as amended as of July 1, 1995 1996, (and no future editions), with the exception of §§ 260.1(b)(4) through (6), 260.20(a), 260.21, 260.22, 260.30, 260.31, 260.32, and 260.33 are incorporated by reference and modified by the following subsections of R18-8-260 and are on file with the Department of Environmental Quality (DEQ) and the Office of the Secretary of State.
 - d. No Change
 - i. No Change
 - ii. No Change
 - iii. No Change
 - iv. No Change
 - e. No Change
 - i. No Change
 - (1) No Change

E. § 260.10, entitled "Definitions", is amended by adding all definitions from § 270.2 to this Section (as incorporated by R18-8-260 and R18-8-270), including the following changes, applicable throughout this Article unless specified otherwise:

- 1. ["Acute Hazardous Waste" means waste found to be fatal to humans in low doses or, in the absence of data on human toxicity, that has been shown in studies to have an oral lethal dose (LD) 50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation lethal concentration (LC) 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 toxicity (rabbit) of less than 200 milligrams per kilogram or that is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness.]
- 2. ["Application" means the standard United States Environmental Protection Agency forms for applying for a permit, including any additions, revisions or modifications to the forms. Application also includes the information required pursuant to §§ 270.14 through 270.29 (as incorporated by R18-8-270, regarding the contents of a Part B HWM facility permit application).]
- 3. ["Biennial report" means "annual report".]
- 4. ["Chapter" means "Article" except in § 264.52(b), see R18-8-264, and § 265.52(b), see R18-8-265.]
- 5. "Closure" means [, for facilities with effective hazardous waste permits, the act of securing a HWM facility pursuant to the requirements of R18-8-264. For facilities subject to interim status requirements, "closure" means the act of securing a HWM facility pursuant to the requirements of R18-8-265.]
- 6. ["Concentration" means the amount of a substance in weight contained in a unit volume or weight.]
- 7. ["Department" means the Department of Environmental Quality or the DEQ.]
- 8. "Department of Transportation" or "DOT" means the U.S. Department of Transportation.
- 9. ["Director" or "state Director" means the Director of the Department of Environmental Quality or an authorized representative, except in §§ 262.50 through 262.57, 268.5 through 268.6, 268.42(b), and 268.44 which are non-delegable to the state of Arizona.]
- 10. ["Draft permit" means a document prepared under § 124.6 (as incorporated by R18-8-271(E)) indicating the Director's tentative decision to issue, deny, modify, revoke, reissue, or terminate a permit. A denial of a request for modification, revocation, reissuance or termi-

- nation, as discussed in § 124.5 (as incorporated by R18-8-271(D)), is not a draft permit.]
11. ["Emergency permit" means a permit that is issued in accordance with § 270.61 (as incorporated by R18-8-270).]
 12. ["EPA", "Environmental Protection Agency", "United States Environmental Protection Agency", "U.S. EPA", "EPA HQ", "EPA Regions", and "Agency" mean the DEQ with the following exceptions:
 - a. Any references to EPA identification numbers;
 - b. Any references to EPA hazardous waste numbers;
 - c. Any reference to EPA test methods or documents;
 - e. Any reference to EPA publications;
 - f. Any reference to EPA manuals;
 - g. Any reference to EPA guidance;
 - h. Any reference to EPA Acknowledgment of Consent;
 - i. References in §§ 260.2(b) (as incorporated by R18-8-260(D)(2)); 260.10 (definitions of "Administrator", "EPA region", "Federal agency", "Person", and "Regional Administrator" (as incorporated by R18-8-260(E)); 260, Appendix I (as incorporated by R18-8-260(C)); 260.11(a) (as incorporated by R18-8-260); 261, Appendix IX (as incorporated by R18-8-261(A)); 262.32(b) (as incorporated by R18-8-262(A)); 262.50 through 262.57 (as incorporated by R18-8-262(A)); 262.80 through 262.89 (as incorporated by R18-8-262(A)); 262, Appendix (as incorporated by R18-8-262(A)); 263.10(a) Note (as incorporated by R18-8-263(A)); 264.12(a)(2), 264.71(d), 265.12(a)(2), 265.71(d); 268.1(e)(3) (as incorporated by R18-8-268); 268.5, 268.6, 268.42(b), and 268.44, which are non-delegable to the state of Arizona (as incorporated by R18-8-268); 270.1(a)(1) (as incorporated by R18-8-270); 270.1(b) (as incorporated by R18-8-270(B)); 270.2 (definitions of "Administrator", "Approved program or Approved state", "Director", "Environmental Protection Agency", "EPA", "Final authorization", "Permit", "Person", "Regional Administrator", and "State/EPA agreement") (as incorporated by R18-8-270(A)); 270.3 (as incorporated by R18-8-270(A)); 270.5 (as incorporated by R18-8-270(A)); 270.10(e)(1) through (2) (as incorporated by R18-8-270(A) and R18-8-270(D)); 270.11(a)(3) (as incorporated by R18-8-270(A)); 270.32(a) and (c) (as incorporated by R18-8-270(M) and R18-8-270(O)); 270.51 (as incorporated by R18-8-270(P)); 270.72(a)(5) and (b)(5) (as incorporated by R18-8-270(A)); 124.1(f) (as incorporated by R18-8-271(B)); 124.5(d) (as incorporated by R18-8-271(D)); 124.6(e) (as incorporated by R18-8-271(E)); 124.10(c)(1)(ii) (as incorporated by R18-8-271(I)); and 124.13 (as incorporated by R18-8-271(L)).]
 13. ["Federal Register" means a daily or weekly major local newspaper of general circulation, within the area affected by the facility or activity, except in §§ 260.11(b) (as incorporated by R18-8-260) and 270.10(e)(2) (as incorporated by R18-8-270 (D)).]
 14. ["HWMA" or "State HWMA" means the State Hazardous Waste Management Act, A.R.S. § 49-921 et seq., as amended.]
 15. ["Hazardous Waste Management facility" or "HWM facility" means any facility or activity, including land or appurtenances thereto, that is subject to regulation under this Article.]
 16. ["Key employee" means any person employed by an applicant or permittee in a supervisory capacity or empowered to make discretionary decisions with respect to the solid waste or hazardous waste operations of the applicant or permittee. Key employee does not include an employee exclusively engaged in the physical or mechanical collection, transportation, treatment, storage, or disposal of solid or hazardous waste.]
 17. ["National" means "state" in §§ 264.1(a) and 265.1(a) (as incorporated by R18-8-264 and R18-8-265).]
 18. ["Off-site" means any site that is not on-site.]
 19. ["Permit" means an authorization, license, or equivalent control document issued by the DEQ to implement the requirements of this Article. Permit includes "permit-by-rule" in § 270.60 (as incorporated by R18-8-270) and "emergency permit" in § 270.61 (as incorporated by R18-8-270), and it does not include interim status as in § 270.70 (as incorporated by R18-8-270) or any permit which has not yet been the subject of final action, such as a "draft permit" or a "proposed permit."]
 20. ["Permit-by-rule" means a provision of these rules stating that a facility or activity is considered to have a HWM facility permit if it meets the requirements of the provision.]
 21. ["Physical construction" means excavation, movement of earth, erection of forms or structures, or similar activity to prepare a HWM facility to accept hazardous waste.]
 22. ["RCRA", "Resource Conservation and Recovery Act", "Subtitle C of RCRA", "RCRA Subtitle C", or "Subtitle C" when referring either to an operating permit or to the federal hazardous waste program as a whole, mean the "State Hazardous Waste Management Act, A.R.S. § 49-921 et seq., as amended" with the following exceptions:
 - a. Any reference to a specific provision of "RCRA", "Resource Conservation and Recovery Act", "Subtitle C of RCRA", "RCRA Subtitle C", or "Subtitle C";
 - b. References in §§ 260.10 (definition of "Act or RCRA") (as incorporated by R18-8-260(E); 260, Appendix I, (as incorporated by R18-8-260(C)); 261, Appendix IX, (as incorporated by R18-8-261(A)); 262, Appendix, (as incorporated by R18-8-262(A)); 270.1(a)(2) (as incorporated by R18-8-270(A)); 270.2, definition of "RCRA", (as incorporated by R18-8-270(A)); and 270.51, "EPA-issued RCRA permit", (as incorporated by R18-8-270(P)).]
 23. [Following any references to a specific provision of "RCRA", "Resource Conservation and Recovery Act", or "Subtitle C", the phrase "or any comparable provisions of the state Hazardous Waste Management Act, A.R.S. §49-921 et seq., as amended" shall be deemed to be added except in §§ 270.72(a) (5) and (b) (5) (as incorporated by R18-8-270(A)).]
 24. ["RCRA § 3005(a) and (e)" means "A.R.S. § 49-922".]

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25. ["RCRA §§ 3007" means "A.R.S. § 49-922".]
 26. ["Recyclable Materials" mean hazardous wastes that are recycled.]
 27. ["Region" or "Region IX" means "state" or "state of Arizona".]
 28. ["Schedule of compliance" means a schedule of remedial measures included in a permit, including an enforceable sequence of interim requirements, such as actions, operations, or milestone events, leading to compliance with the HWMA and these rules.]
 29. ["Site" means the land or water area where any facility or activity is physically located or conducted, including adjacent land used in connection with such a facility or activity.]
 30. ["State", "authorized state", "approved state", or "approved program" means the state of Arizona with the following exceptions:
References at §§ 260.10, definitions of "person", "state", and "United States", (as incorporated by R18-8-260(E)); 262 (as incorporated by R18-8-262(A));
264.143(e) (1) (as incorporated by R18-8-264(A));
264.145(e) (1) (as incorporated by R18-8-264(A));
264.147(a) (1) (ii) (as incorporated by R18-8-264(A));
264.147(b) (1) (ii) (as incorporated by R18-8-264(A));
264.147(g) (2) (as incorporated by R18-8-264(A));
264.147(i) (4) (as incorporated by R18-8-264(A));
265.143(d) (1) (as incorporated by R18-8-265(A));
265.145(d) (1) (as incorporated by R18-8-265(A));
265.147(a) (1) (ii) (as incorporated by R18-8-265(A));
265.147(g) (2) (as incorporated by R18-8-265(A));
265.147(i) (4) (as incorporated by R18-8-265(A));
and
270.2, definitions of "Approved program or Approved state", "Director", "Final authorization", "Person", and "state" (as incorporated by R18-8-270(A)).]
 31. ["The effective date of these regulations" means the following dates: "May 19, 1981", in §§ 265.112(a) and (d), 265.118(a) and (d), 265.142(a) and 265.144(a) (as incorporated by R18-8-265); "November 19, 1981", in §§ 265.112(d) and 265.118(d) (as incorporated by R18-8-265); and "January 26, 1983", in § 270.1(c) (as incorporated by R18-8-270).]
 32. ["TSD facility" means a "Hazardous Waste Management facility" or "HWM facility".]
- F.** § 260.10, entitled "Definitions", as amended by subsection E also is amended as follows, with all definitions in § 260.10 (as incorporated by R18-8-260), applicable throughout this Article unless specified otherwise.
1. "Act" or ["the Act" means the state Hazardous Waste Management Act or HWMA, except in R18-8-261(B) and R18-8-262(B).]
 2. "Administrator", "Regional Administrator", "state Director", or "Assistant Administrator for Solid Waste and Emergency Response" mean the [Director or the Director's authorized representative, except in §§ 260.10, definitions of "Administrator", "Regional Administrator", and "hazardous waste constituent" (as incorporated by R18-8-260(E));
 - 261, Appendix IX (as incorporated by R18-8-261(A));
 - 262, Subpart E;
 - 262, Subpart H;
 - 262, Appendix (as incorporated by R18-8-262);
 - 264.12(a) (as incorporated by R18-8-264(A));
 - 265.12(a) (as incorporated by R18-8-265(A));
 - 268.5, 268.6, 268.42(b), and 268.44, which are nondelegable to the state of Arizona (as incorporated by R18-8-268);
 - 270.2, definitions of "Administrator", "Director", "Major facility", "Regional Administrator", and "State/EPA agreement" (as incorporated by R18-8-270(A));
 - 270.3 (as incorporated by R18-8-270(A));
 - 270.5 (as incorporated by R18-8-270(A));
 - 270.10(e)(1), (2), and (4) (as incorporated by R18-8-270(A) and R18-8-270(D));
 - 270.10(f) and (g) (as incorporated by R18-8-270(A) and R18-8-270(E));
 - 270.11(a)(3) (as incorporated by R18-8-270(A));
 - 270.14(b)(20) (as incorporated by R18-8-270(A));
 - 270.32(b)(2) (as incorporated by R18-8-270(N));
 - 270.51 (as incorporated by R18-8-270(A));
 - 124.5(d) (as incorporated by R18-8-271(D));
 - 124.6(e) (as incorporated by R18-8-271(E));
 - 124.10(b) (as incorporated by R18-8-271(I));
3. "Facility" [or "activity" means:
 - a. Any HWM facility or other facility or activity, including] all contiguous land, structures, appurtenances, and improvements on the land which are used for treating, storing, or disposing of hazardous waste, that is subject to regulation under the HWMA program. A facility may consist of several treatment, storage, or disposal operational units (e.g., 1 or more landfills, surface impoundments, or combinations of them).
 - b. For the purposes of implementing corrective action under 40 CFR 264.101 (as incorporated by R18-8-264), all contiguous property under the control of the owner or operator seeking a permit under Subtitle C of RCRA. This definition also applies to facilities implementing corrective action under RCRA Section 3008(h).
 4. "New HWM facility" or "new facility" means a HWM facility which began operation, or for which construction commenced, [after November 19, 1980].
 5. "Person" means an individual, trust, firm, joint stock company, federal agency, corporation, including a government corporation, [or a limited liability corporation], partnership, association, state, municipality, commission, political subdivision of a state, or any interstate body, [state agency, or an agent or employee thereof].
 6. "United States" means [Arizona except the following:
 - a. References in §§ 262.50, 262.51, 262.53(a), 262.54(c), 262.54(g)(2), 262.54(i), 262.55(a), 262.55(c), 262.56(a)(4), 262.60(a), and 262.60(b)(2) (as incorporated by R18-8-262).
 - b. All references in Part 263 (as incorporated by R18-8-263), except §§263.10(a) and 263.22(c).]
 7. "Universal waste" means any of the hazardous wastes that are subject to universal waste requirements in 40 CFR 273 (as incorporated by reference by R18-8-273)

and described in 40 CFR 273.2 through 40 CFR 273.4 and in A.A.C. R18-8-273(D) and R18-8-273(E).

G. No Change

H. No Change

I. No Change

J. § 260.30, entitled "Variances from classification as a solid waste," is replaced by the following: Any person wishing to submit a variance petition shall submit the petition, under this subsection, to the EPA. Where the administrator of EPA has granted a variance from classification as a solid waste pursuant to 40 CFR 260.30, 260.31, and 260.33, the director shall accept the determination, provided the director determines the action is consistent with the policies and purposes of the HWMA.

K. § 260.32, entitled "Variances to be classified as a boiler," is replaced by the following: Any person wishing to submit a variance petition shall submit the petition, under this subsection, to the EPA. Where the administrator of EPA has granted a variance from classification as a boiler pursuant to 40 CFR 260.32 and 260.33, the director shall accept the determination, provided that the director determines the action is consistent with the policies and purposes of the HWMA.

J.L. 40 CFR § 260.41, entitled "Procedures for case-by-case regulation of hazardous waste recycling activities," is amended by deleting the following from the end of the 6th, and the 7th and 8th sentences of paragraph (a):

"Or unless review by the Administrator is requested. The order may be appealed to the administrator by any person who participated in the public hearing. The Administrator may choose to grant or to deny the appeal."

M. As required by A.R.S. § 49-929, generators and transporters of hazardous waste shall register annually with DEQ and submit the appropriate registration fee, prescribed below, with their registration:

1. A hazardous waste transporter that picks-up or delivers hazardous waste in Arizona shall pay \$200 by March 1 of the year following the date of the pick-up or delivery;
2. A large-quantity generator which generated 1,000 kilograms or more of hazardous waste in any month of the previous calendar year shall pay \$300; or
3. A small-quantity generator which generated 100 kilograms or more but less than 1,000 kilograms of hazardous waste in any month of the previous year shall pay \$100.

R18-8-261. Identification and Listing of Hazardous Waste

A. All of 40 CFR 261 and accompanying appendices, as amended as of July 1, 1996 1995 (and no future editions), with the exception of § 261.5(j), are incorporated by reference and modified by the following subsections of R18-8-261 and are on file with the DEQ and the Office of the Secretary of State. In addition, all amendments to Part 261 and its appendices in 61 Fed. Reg. 59932, November 25, 1996, are incorporated by reference and on file with the DEQ and the Office of Secretary of State.

B. No Change

C. No Change

D. No Change

E. No Change

F. No change

G. § 261.5, entitled "Special requirements for hazardous waste generated by conditionally exempt small quantity generators", paragraph (f)(3) is amended as follows:

- (3) A conditionally exempt small quantity generator may either treat or dispose of [the] acute hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage, or disposal facility, either of which is:

(i) Permitted under part 270 of this Chapter [(as incorporated by R18-8-270)];

(ii) In interim status under parts 270 and 265 of this Chapter [(as incorporated by R18-8-270 and R18-8-265)];

(iii) Authorized to manage hazardous waste by a state with a hazardous waste management program approved under part 271 of this Chapter;

(iv) Permitted, licensed, or registered by a state to manage municipal [or industrial solid waste [and approved by the owner or operator of the solid waste facility to accept acute hazardous waste from conditionally exempt small quantity generators that have not been excluded from disposing of their waste at such a facility pursuant to applicable provisions of the Solid Waste Management Act, A.R.S. §§ 49-701 through 49-791 and] is subject to Part 258 of this Chapter;

(v) Permitted, licensed, or registered by a state to manage non-municipal non-hazardous waste and if managed in a non-municipal non-hazardous waste disposal unit after January 1, 1998, is subject to the requirements in §§ 257.5 through 257.30 of this chapter; or

(v)(vi) A facility which:

(A) Beneficially uses or reuses, or legitimately recycles or reclaims its waste; or

(B) Treats its waste prior to beneficial use or reuse, or legitimate recycling or reclamation; or

(vi)(vii) For universal waste managed under § 273 [(as incorporated by R18-8-273)], a universal waste handler or destination facility subject to the requirements of § 273.

H. § 261.5, entitled "Special requirements for hazardous waste generated by conditionally exempt small quantity generators", paragraph (g) is amended as follows:

(g) In order for hazardous waste[, other than acute hazardous waste,] generated by a conditionally exempt small quantity generator in quantities of less than 100 kilograms of hazardous waste during a calendar month to be excluded from full regulation under this [subsection], the generator [shall] comply with the following requirements:

(1) § 262.11 [(as incorporated by R18-8-262)];

(2) The conditionally exempt small quantity generator may accumulate hazardous waste on-site. If [such generator] accumulates at any time more than a total of 1000 kilograms of hazardous wastes, all of those accumulated [hazardous] wastes are subject to regulation under the special provisions of § 262 applicable to generators of between 100 kg and 1000 kg of hazardous waste in a calendar month as well as the requirements of §§ 263 through 266, 268, 270, and 124 [as incorporated by R18-8-262, R18-8-263 through R18-8-266, R18-8-268, R18-8-270, and R18-8-271)] and the applicable notification requirements of section 3010 of RCRA. The time period of § 262.34(d) [(as incorporated by R18-8-262)] for accumulation of wastes on-site begins for a conditionally exempt small quantity generator when the accumulated wastes exceed 1000 kilograms;

(3) A conditionally exempt small quantity generator may either treat or dispose of [its] hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage, or disposal facility, either of which is:

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- (i) Permitted under part 270 of this Chapter [(as incorporated by R18-8-270)];
- (ii) In interim status under parts 270 and 265 of this Chapter [(as incorporated by R18-8-270 and R18-8-265)];
- (iii) Authorized to manage hazardous waste by a State with a hazardous waste management program approved under part 271 of this Chapter;
- (iv) Permitted, licensed, or registered by a state to manage municipal [or industrial solid waste [and approved by the owner or operator of the solid waste facility to accept hazardous waste from conditionally exempt small quantity generators who have not been excluded from disposing of their waste at such a facility pursuant to applicable provisions of the Solid Waste Management Act, A.R.S. §§ 49-701 through 49-791 and] is subject to Part 258 of this Chapter;
- (v) Permitted, licensed, or registered by a state to manage non-municipal non-hazardous waste and, if managed in a non-municipal non-hazardous waste disposal unit after January 1, 1998, is subject to the requirements in §§ 257.5 through 257.30 of this chapter; or
- (vi)(vi) A facility which:
 - (A) Beneficially uses or reuses, or legitimately recycles or reclaims its waste; or
 - (B) Treats its waste prior to beneficial use or reuse, or legitimate recycling or reclamation; or
- (vi)(vii) For universal waste managed under part 273 of this Chapter [(as incorporated by R18-8-273)], a universal waste handler or destination facility subject to the requirements of part 273 of this Chapter.

- I. No Change
- J. No Change
- K. No Change
- L. No Change

R18-8-262. Standards Applicable to Generators of Hazardous Waste

- A. All of 40 CFR 262, and the accompanying appendix, as amended as of July 1, 1995 1996, (and no future editions), are incorporated by reference and modified by the following subsections of R18-8-262, and are on file with the DEQ and the Office of the Secretary of State. In addition, all amendments to Part 262 and its appendices in 61 Fed. Reg. 59932, November 25, 1996, are incorporated by reference and on file with the DEQ and the Office of Secretary of State.
- B. No Change
 - 1. No Change
 - 2. No Change
 - 3. No Change
- C. No Change
- D. No Change
- E. No Change
- F. No Change
- G. No Change
- H. No Change
 - 1. No Change
 - 2. No Change
- I. § 262.42, entitled "Exception reporting," is amended by replacing "The Exception Report must include:" in paragraph (a)(2) with the following: "The Exception Report shall be sub-

mitted to DEQ within 45 days following the end of the month of shipment of the waste and shall include:"

- J. § 262.42, entitled "Exception reporting," paragraph (b) is amended by adding the following sentence to the end of the paragraph: "This submission to DEQ shall be made within 60 days following the end of the month of shipment of the waste.

- I.K. No Change
- J.L. No Change
- K.M. No Change
- L.N. No Change

R18-8-263. Standards Applicable to Transporters of Hazardous Waste

- A. All of 40 CFR 263, as amended as of July 1, 1995 1996, (and no future editions), is incorporated by reference and modified by the following subsections of R18-8-263, and on file with the DEQ and the Office of the Secretary of State.
- B. No Change
- C. No Change
- D. No Change
- E. No Change

R18-8-264. Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities

- A. All of 40 CFR 264, and accompanying appendices, as amended as of July 1, 1995 1996, (and no future editions), with the exception of §§ 264.1(d) and (f), 264.149 - 264.150, and 264.301(l), are incorporated by reference, and modified by the following subsections of R18-8-264, and are on file with the DEQ and the Office of the Secretary of State. In addition, all amendments to Part 264 and its appendices in 61 Fed. Reg. 59932, November 25, 1996, are incorporated by reference and on file with the DEQ and the Office of Secretary of State.
- B. No Change
- C. No Change
 - 1. No Change
 - 2. No Change
- D. No Change
- E. No Change
- F. No Change
- G. No Change
- H. No Change
 - 1. No Change
 - 2. No Change
- I. No Change
- J. No Change
- K. No Change
- L. No Change
- M. No Change
- N. No Change
 - 1. No Change
 - 2. No Change
 - 3. No Change
 - 4. No Change
 - 5. No Change
 - 6. No Change

R18-8-265. Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities

- A. All of 40 CFR 265, and accompanying appendices, as amended as of July 1, 1995 1996, (and no future editions), with the exception of §§ 265.1(c)(2), 265.1(c)(4), 265.149, 265.150, and 265.430, are incorporated by reference and modified by the following subsections of R18-8-265, and are on file with the DEQ and the Office of the Secretary of State. In addition, all amendments to Part 265 and its appendices in 61

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FR 59932, November 25, 1996, are incorporated by reference and on file with the DEQ and the Office of Secretary of State.

- B. No Change
- C. No Change
 - 1. No Change
 - 2. No Change
- D. No Change
- E. No Change
- F. No Change
- G. No Change
- H. No Change
- I. No Change
- J. No Change
 - 1. No Change
 - 2. No Change
 - 3. No Change
- K. No Change
 - 1. No Change
- L. No Change

R18-8-266. Standards for the Management of Specific Hazardous Wastes and Specific Hazardous Waste Management Facilities

- A. All of 40 CFR 266, and accompanying appendices as amended as of July 1, 1995 1996, (and no future editions), are incorporated by reference and are on file with the DEQ and the Office of the Secretary of State.
- B. No Change

R18-8-268. Land Disposal Restrictions

All of 40 CFR 268, and accompanying appendices, as amended as of July 1, 1995 1996, (and no future editions), with the exception of 40 CFR 268(B), are incorporated by reference and are on file with the DEQ and the Office of the Secretary of State. In addition, all amendments to Part 268 and its appendices in 61 Fed. Reg. 43924, August 26, 1996, are incorporated by reference and on file with the DEQ and the Office of Secretary of State.

R18-8-270. The Hazardous Waste Permit Program

- A. All of 40 CFR 270, as amended as of July 1, 1995 1996 (and no future editions), with the exception of §§ 270.1(a), 270.1(c)(1)(i), 270.3, 270.10(g)(1)(i), 270.60(a) and (b), and 270.64, is incorporated by reference and modified by the following subsections of R18-8-270 and is on file with the DEQ and the Office of the Secretary of State. In addition, all amendments to Part 270 and its appendices in 61 Fed. Reg. 59932, November 25, 1996, are incorporated by reference and on file with the DEQ and the Office of Secretary of State.
- B. No Change
 - 1. No Change
 - a. No Change
 - b. No Change
 - c. No Change
 - 2. No Change
 - a. No Change
 - b. No Change
- C. No Change
- D. No Change
- E. No Change
- F. No Change
- G. No Change
 - 1. No Change
 - a. No Change
 - b. No Change
 - c. No Change
 - d. No Change
 - 2. No Change

- 3. No Change
 - a. No Change
 - b. No Change
 - c. No Change
- 4. No Change
- 5. No Change
- 6. No Change
 - a. No Change
 - b. No Change
- 7. No Change
 - a. No Change
 - b. No Change
 - c. No Change
 - d. No Change
 - e. No Change
 - f. No Change
 - g. No Change
 - h. No Change
 - i. No Change
 - j. No Change
- 8. No Change
- 9. No Change
- H. No Change
- I. No Change
- J. No Change
 - [(22)(23) No Change
 - (23)(24)(i) No Change
 - (A) No Change
 - (B) No Change
 - (ii) No Change
- K. No Change
- L. No Change
- M. No Change
- N. No Change
- O. No Change
- P. No Change
- Q. No Change

R18-8-271. Procedures for Permit Administration

- A. All of 40 CFR 124 and the accompanying appendix as amended as of July 1, 1995 1996, (and no future editions), relating to HWM facilities, with the exception of §§ 124.1(b) through (e), 124.2, 124.4, 124.16, 124.20 and 124.21, are incorporated by reference and modified by the following subsections of R18-8-271 and are on file with the DEQ and the Office of the Secretary of State.
- B. No Change
- C. No Change
- D. No Change
- E. No Change
- F. No Change
- G. No Change
- H. No Change
- I. No Change
- J. No Change
- K. No Change
- L. No Change
- M. No Change
- N. No Change
- O. No Change
- P. No Change
- Q. No Change
- R. §124.31(a) entitled "Pre-application public meeting and notice" is amended by deleting the following sentence:
 "For the purpose of this section only, 'hazardous waste management units over which EPA has permit issuance authority' refers to hazardous waste management units

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for which the State where the units are located has not been authorized to issue RCRA permits pursuant to 40 CFR 271."

- S. § 124.31(a) entitled "Public notice requirements at the application stage" is amended by deleting the following sentence:

"For the purpose of this section only, 'hazardous waste management units over which EPA has permit issuance authority' refers to hazardous waste management units for which the State where the units are located has not been authorized to issue RCRA permits pursuant to 40 CFR 271."

- T. § 124.33(a) entitled "Information repository" is amended by deleting the following sentence:

"For the purpose of this section only, 'hazardous waste management units over which EPA has permit issuance authority' refers to hazardous waste management units for which the State where the units are located has not been authorized to issue RCRA permits pursuant to 40 CFR 271."

R18-8-273. Standards for Universal Waste Management

- A. All of 40 CFR 273, as amended as of July 1, 1995 1996 (and no future editions), is incorporated by reference and modified by the following subsections of R18-8-273 and is on file with the DEQ and the Office of the Secretary of State.

- B. § 273.1, entitled "Scope" paragraph (a) is amended by adding the following:

(4) Mercury-containing lamps as described in R18-8-273(D).

- C. Applicability-mercury-containing lamps. The requirements of this section apply to persons managing mercury-containing lamps as described in R18-8-273(D), except those listed in paragraph a of this subsection.

1. Lamps not regulated under R18-8-273. The requirements of this Section do not apply to persons managing the following lamps:

- a. Lamps that are not yet wastes under 40 CFR 261 (as incorporated by R18-8-261). Subsection (C)(2) describes when lamps become wastes.
- b. Lamps that are not hazardous wastes. A lamp is a hazardous waste if it exhibits 1 or more of the characteristics identified in 40 CFR 261, Subpart C (as incorporated by R18-8-261).

2. Generation of waste lamps.

- a. A used or spent mercury-containing lamp becomes a waste on the date it is removed from service.
- b. An unused mercury-containing lamp becomes a waste on the date the handler decides to discard it.

- D. § 273.6, entitled "Definitions" is amended by adding the following definition: "Mercury-containing lamp" means the bulb or tube portion of a lighting device specifically designed to produce radiant energy, most often in the ultraviolet (UV), visible, and infrared (IR) regions of the electromagnetic spectrum. Four common mercury-containing lamps are fluorescent lamps, sodium-vapor lamps, high- and low-pressure mercury vapor lamps, and high intensity discharge (HID) lamps.

- E. § 273.6, entitled "Definitions" is amended by adding the following to the definition of universal waste:

(d) Mercury-containing lamps as described in subsection (D) in this Section.

- F. § 273.13, entitled "Waste management" is amended by adding paragraph (d) as follows:

(d) Universal waste lamps. A small quantity handler of universal waste shall manage universal waste lamps in a way that prevents releases of any universal waste or component of any universal waste to the environment, as follows:

- (1) A small-quantity handler shall manage universal waste lamps in a way that minimizes lamp breakage. The small-quantity handler shall:

- (i) Contain unbroken lamps in packaging that will minimize breakage during normal handling, and
- (ii) Contain broken lamps in packaging that will minimize releases of lamp fragments and residues.

- (2) A small-quantity handler of universal waste lamps shall immediately contain all releases of residues from hazardous waste lamps.

- (3) A small-quantity handler of universal waste lamps shall determine whether any materials (that is, mercury, residues, or other solid wastes) resulting from the release exhibit a characteristic of hazardous waste, and if so, shall manage the waste in accordance with all applicable requirements in 40 CFR 260 through 272 (as incorporated by R18-8-260 through R18-8-271).

- (4) If the mercury, residues, or other solid waste is not hazardous, the handler may manage the waste in any way that is in compliance with applicable federal, state, or local solid waste regulations.

- G. § 273.14, entitled "Labeling/markings" is amended by adding paragraph (e) as follows:

(e) A universal waste lamp, or a container in which the lamps are contained shall be labeled or marked clearly with any 1 of the following phrases: "Universal Waste Mercury Lamp(s)," or "Waste Mercury Lamp(s)," or "Used Mercury Lamp(s)."

- H. § 273.33, entitled "Waste management" is amended by adding paragraph (d) as follows:

(d) Universal waste lamps. A large-quantity handler of universal waste shall manage universal waste lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:

- (1) A large-quantity handler shall manage universal waste lamps in a way that minimizes lamp breakage. The large-quantity handler shall:

- (i) Contain unbroken lamps in packaging that will minimize breakage during normal handling, and
- (ii) Contain broken lamps in packaging that will minimize releases of fragments and residues.

- (2) A large-quantity handler of universal lamps shall immediately contain all releases of residues from hazardous waste lamps.

- (3) A large-quantity handler of universal waste lamps shall determine whether any materials (that is, mercury, residues, or other solid wastes) resulting from the release exhibit a characteristic of hazardous waste, and if so, shall manage the waste in accordance with all applicable requirements in 40 CFR 260 through 272 (as incorporated by R18-8-260 through R18-8-271).

- (4) If the mercury, residues, or other solid waste is not hazardous, the handler may manage the waste in any way that is in compliance with applicable federal, state, or local solid waste regulations.

- I. § 273.34, entitled "Labeling/markings" is amended by adding paragraph (e), as follows:

(e) Universal waste lamps (that is, each lamp), or a container in which the lamps are contained, shall be labeled or marked clearly with any 1 of the following phrases: "Uni-

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versal Waste Mercury Lamp(s)." or "Waste Mercury Lamp(s)." or "Used Mercury Lamp(s)."

- I. § 273.60, entitled "Applicability" is amended by adding paragraph (c) as follows:

(c) The owner or operator of a destination facility that manages mercury-containing waste lamps as a universal waste, is in operation as of the effective date of this rule, and required to submit a hazardous waste permit applica-

tion shall submit Parts A and B of the application no later than 180 days following the effective date of this rule. Until such time that the Director takes final action on the application, the facility shall manage universal waste lamps in accordance with the document entitled "Arizona Department of Environmental Quality Compliance Agreement for a Mercury-Containing Waste Lamps Processing/Recycling Facility."